



#### **Executive Summary & Detailed Report**

## Evaluation of the Indiana Medicaid Preferred Drug List (PDL) Program

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Outcomes Analyses
Conducted by:
ACS State Healthcare Solutions

For

State of Indiana
Office of Medicaid Policy and Planning
And
Indiana Medicaid DUR Board

By: George Olson, M.S. Michelle Laster-Bradley, Ph.D., M.S., R.Ph. Jay Weaver, Pharm.D., M.P.H. Jim Adkins, M.S., R.Ph.



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#### **EXECUTIVE SUMMARY**

#### Introduction

The cost of providing prescription drug services for traditional Medicaid fee-for-service (FFS) recipients has risen dramatically. Nevertheless, the Indiana legislature, the Office of Medicaid Policy and Planning (OMPP), and the Indiana Medicaid Drug Utilization Review (DUR) Board have demonstrated a commitment to address the health care needs for the citizens of Indiana. A major focus for the OMPP and Medicaid DUR Board has been to maximize prescription drug products/services while minimizing the cost to the State of Indiana.

In January 2002, the State of Indiana created a prior authorization (PA) program, the Indiana Rational Drug Program (IRDP), designed to control costs while ensuring appropriate use of prescription drugs for Medicaid recipients. *Indiana Senate Enrolled Act No. 228 (SEA 228)* of the 2002 General Assembly provided for the creation and implementation of a preferred drug list (PDL) under Indiana Medicaid, with prior authorization for drugs not included on the PDL. The PDL program built upon the intent of the IRDP, but encompassed a much wider range of prescription drug classes. As with the IRDP, the purpose of the PDL is to ensure that Indiana Medicaid recipients receive clinically appropriate prescription drugs, while minimizing the cost incurred. The PDL program was introduced in August 2002 for the Primary Care Case Management (PCCM) Program and the Fee-for-Service Program.

The PDL selection process is based upon a non-biased, clinical review of medications within a given therapeutic class. "Preferred" are chosen based on clinical efficacy, safety and cost<sup>1</sup>. The Indiana Medicaid Therapeutics Committee (T Committee), composed of physicians and pharmacists, reviews the clinical and economic data of each applicable medication. The T Committee submits selection recommendations to the Indiana Medicaid Drug Utilization Review (DUR) Board for approval.

In finalizing selection of one or more preferred drugs within a therapeutic class, the T Committee and DUR Board give primary consideration to clinical efficacy or therapeutic appropriateness. Then they also consider cost effectiveness, including consideration of the PDL program's cost implications on other components of the State's Medicaid program, such as access to care and potential cost shifting.

Medications classified as nonpreferred may be permitted upon request from the prescribing physician, using the published prior authorization process. The Indiana PDL program currently consists of 52 therapeutic drug classes implemented over a 13-month period beginning in August 2002. Then in August 2003, a process of continual improvement to the PDL program began, with biannual reviews of PDL classes, and analyses of health outcomes and cost implications.

<sup>&</sup>lt;sup>1</sup> Cost is net of federal rebates.



#### **Objectives**

The objective of this report is to determine the overall impact of the PDL in accordance with Indiana Code 12-15-35-28(h).

The four primary objectives are to evaluate:

- Any increase in Medicaid physician, laboratory, or hospital costs or in other state funded programs as a result of the preferred drug list.
- The impact of the preferred drug list on the ability of a Medicaid recipient to obtain prescription drugs.
- The number of times prior authorization was requested, and the number of times prior authorization was: (A) approved and (B) disapproved.
- The cost of administering the preferred drug list.

#### **Research Questions**

- 1. Were there changes in physician office visits, laboratory services, emergency visits or hospital expenditures associated with the Indiana PDL program?
- 2. Does the PDL program affect a recipient's ability to obtain prescription drugs?
- 3. How many PA's were requested? How many approved/denied?
- 4. What is the net pharmacy benefit savings associated with the PDL program?

#### **Results Summary**

#### Summary: Impact of PDL on Health Outcomes of Indiana Medicaid Recipients

Overall medical expenditures of recipients affected by the PDL program were not associated with any statistically significant differences when compared to recipients not affected by the PDL program. Seven therapeutic drug classes were evaluated for differences in medical expenditures: ACE Inhibitors; Alpha/beta Adrenergic Blocker Antihypertensives; Calcium Channel Blocker Antihypertensives; Loop diuretics; Platelet Aggregation Inhibitors; Thiazolidinediones; and Triptans. These therapeutic drug classes were evaluated over a 6-month pre- and a 6-month post-implementation of the PDL program. Of the therapeutic classes evaluated, the evidence does not demonstrate any statistically significant change in overall medical expenditures. Generally, recipients affected by the PDL program did not incur a statistically significant difference in overall medical expenditures when compared to recipients not affected by the PDL program. Analyses were performed on the specific expenditures include: prescriber office visits, inpatient hospital admissions, emergency room services, and laboratory procedures. When examining specific medical service types, there is no evidence at 6-months post-



PDL implementation to suggest that significant cost shifting to other health care providers, laboratories, emergency room services or hospitals is occurring on a wide, systematic scale. There were, however, two areas of statistically significant differences between groups when examining the specific medical service types (laboratory expenditures in the ACE inhibitors, p=0.002 and physician office expenditures in the platelet aggregation inhibitors, p=0.001). Since there was a claims lag, data are only for 6-months, and we can only determine association, not causality, these specific medical service types have been noted to watch in future iterations of this evaluation.

## Attrition Analysis Summary: Does the PDL program affect a recipient's ability to obtain prescription drugs?

Twenty-three classes contained enough claims data after PDL implementation to assess the PDL program's impact on users' access to medications. Recipients involved in the PDL program either switched to a preferred medication or received a prior authorization to continue with their nonpreferred medication. Of the 188,508 monthly recipients followed, only 1485 (0.78%) experienced a denied claim with no paid claim for a related medication within 30 days. Further, denials for a given class diminished monthly as providers gained experience with the program. It is impossible to know from pharmacy claims data what portion of these dropped claims were duplicate or unnecessary therapies. Overall, this number suggests a minimum impact on PDL users.

However, since pharmacy claims data were the only source of information available to perform this analysis, it is impossible to determine which delay/terminations were clinically appropriate. Claims data does not allow full explanation for the therapy interruptions. For example, there are many potential reasons other than PDL such as: physician sampling of medications, other third party liability, patient compliance, or changes in patient therapy.

#### **Prior Authorization Summary:**

Between August 2002 when the PDL program began to December 31, 2002, there were 17,866 Preferred Drug List (PDL) program prior authorizations (PA's) requested, 17,775 were approved (99.5%) and 91 were denied (0.5%).

During the calendar year 2003 (1/1/03 to 12/31/03) there were 53,604 PDL program prior authorizations requested. Of the 53,604 PA's requested, 52,054 were approved (97.1%), 165 were denied (0.3%) and 1,385 were suspended (2.6%).

Between January 1, 2004 and April 30, 2004, there were 18,470 PDL program prior authorizations (PA's) requested. Of the 18,470 PA's requested, 18,200 were approved (98.5%), 91 were denied (0.5%) and 179 were suspended (1.0%).

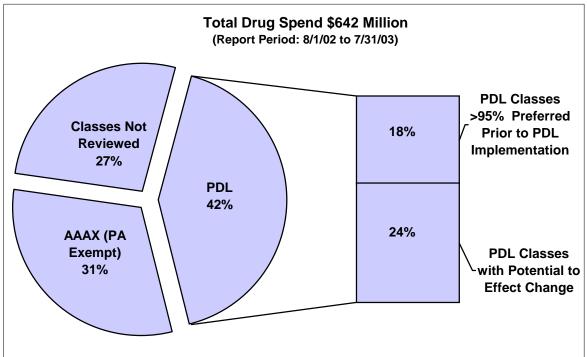
Pharmacy Benefit Expenditure Summary: What is the net pharmacy benefit savings associated with the PDL program?



The total pharmacy expenditures for the Primary Care Case Management and Fee-For-Service Medicaid program for the annual period of 8/1/02 to 7/31/03 was \$642<sup>2</sup> million (Chart 1.1). This figure includes four separate categories:

- PDL Applicable (23.9%) \$154 m
- AAAX<sup>3</sup> (PA exempt) (31.1%) \$200 m
- Classes Not Reviewed<sup>4</sup> (27%)
- PDL classes with limited<sup>5</sup> benefit @ >95% preferred prior to implementation (18%) \$116 m

Chart 1.1 Partitions of Total Drug Spend (\$642 Million) from 8/1/02 to 7/31/03



Total annualized pharmacy benefit payment reductions from 50 of 52<sup>6</sup> PDL classes implemented from August 2002 through August 2003 are estimated at \$12.4 million. CMS (standard Federal) rebate reductions are estimated to be \$3.5 million for a net annualized pharmacy benefit payment reduction (or expenditure savings) of \$8.9 million.

Overall, the preferred drug market share shifted from approximately 75.2% to 95.8% during this period. In 7 of 50 PDL classes studied, preferred drugs selected by the Indiana Medicaid Therapeutics Committee and accepted by the DUR Board did not

<sup>&</sup>lt;sup>2</sup> Figures from 8/1/02 to 7/31/03 claims data.

<sup>&</sup>lt;sup>3</sup> These medications are exempt from the PDL per statute – anti-anxiety, antidepressant, antipsychotic and cross-indicated drugs.

<sup>&</sup>lt;sup>4</sup> Drug classes of medications not on the PDL program from August 2002 to August 2003.

<sup>&</sup>lt;sup>5</sup> Over 95% of market share was preferred medications prior to implementation

<sup>&</sup>lt;sup>6</sup> Two classes had too small number of claims paid (9 claims) by September 2003 to evaluate.



provide the opportunity for any market share change because all drugs within the class were selected as preferred.

Pharmacy benefit net expenditure savings were sensitive to cost differences between preferred and nonpreferred drugs. Net expenditure increases were associated with some therapeutic classes where the net expenditure per preferred drug claim was greater than net expenditure per nonpreferred drug claim. More expensive PDL drugs were chosen for clinical reasons, based on anticipation of better outcomes. Additionally, some increase in expenditures occurred due to unanticipated rebate or product price changes occurring after the selection of preferred drugs.

#### **Discussion and Conclusions**

In response to increases in prescription drug spending and utilization, many public-sector pharmacy benefit programs have been developing and implementing a variety of innovative policy solutions for more effective management of pharmacy benefits. One of the methods that several state Medicaid agencies have implemented is the preferred drug list (PDL) program. The concept behind the PDL program is to improve the quality of pharmaceutical care by ensuring that the most clinically appropriate drug is used, while taking into account the relative costs of the available therapeutically equivalent alternatives. PDL programs can address the problems associated with:

- Recipients who rarely see or pay the true costs of their drugs; and therefore have no incentive to choose less expensive, yet equally effective medications.
- Prescribers who lack current knowledge of the true costs of medications being prescribed.

This evaluation demonstrates that a Preferred Drug List program does decrease spending, with no evidence to suggest an association between the PDL and negative impacts on the quality of care or the ability for recipients to obtain medications. Specifically, there is no evidence at 6-months post-PDL implementation to suggest that significant cost shifting to other health care providers, laboratories, emergency room services or hospitals is occurring on a wide, systematic scale. Furthermore, the market share movement identified through this evaluation suggests that educating prescribers to prescribe and recipients to utilize preferred drugs works. As a result of moving market share to the preferred products, the PDL produced savings.

Although there were documented savings, these savings may have been lessened by three key factors.

• Standard federal rebates – Savings resulting from the PDL policy were reduced after considering the impact of lost CMS federal rebates from some preferred drugs. Higher-priced nonpreferred drugs sometimes had proportionately higher



corresponding CMS rebates. When the drugs with higher rebates lose market share under a PDL program, rebate amounts can be reduced.

• Lack of readily available, timely data for decision support – Data on relative cost-effectiveness and net cost of drug products, after applying rebates, were not readily available at the beginning of the program. In the past, because each manufacturer applies its rebate after-the-fact, only estimates of the true net cost for drugs can be made until several months after sales are completed. ACS has recently employed modeling tools that now allow for better projections of the cost implications of shifting market share among medications in a PDL therapeutic class.

#### • Limits to savings potential:

- o Some PDL classes had a high percentage of pre-implementation usage of the preferred medications offering little opportunity for savings.
- o Some preferred drugs' net costs were higher than the nonpreferred drugs (chosen on clinical advantage).
- o Some preferred drugs' underwent unexpected price increases.

Several solutions have potential to address the reduction of savings from the factors listed above. Savings can best be achieved if a PDL program is combined with methods to increase purchasing power. For example:

- <u>Limit the number of preferred drugs within a given therapeutic class</u> The amount of savings is directly related to the ability to increase the market share of the more favorably priced medication within a therapeutic class. Moreover, the more preferred products, the less opportunity to move market share and therefore less potential for savings. Assuming that medications are clinically equivalent, the smaller the list of preferred drugs, the more potential to move market share and obtain supplemental rebates (discussed below).
- Choose less costly "preferred drugs" Savings from the PDL program are reduced if equally effective, less expensive drugs are not selected as preferred. Opportunities still exist within the current PDL program to choose less costly drugs while maintaining high quality pharmaceutical care. Once equivalent clinical efficacy has been demonstrated within a class, only then should net costs due to rebates be considered. Each alternative mix of preferred drugs can now be analyzed for net savings using tools by the ACS' Health and Economic Outcomes Research Department that were unavailable at the beginning of the PDL program.
- Add supplemental rebates Savings from the PDL program could be enhanced if supplemental rebates are obtained. Supplemental rebates for Medicaid pharmacy claims are a form of state action that increases competition in drug pricing. Increased competition helps drive pricing down in a free market where manufacturers are allowed to set prices in accordance to available competition. In a therapeutic class where numerous brand drugs are found to be clinically equal,



supplemental rebates encourage competition by allowing manufacturers to submit progressively higher rebate bids. The manufacturer benefits from obtaining greater market share while the State benefits financially in the form of supplemental rebates.

- Remove "AAAX" drugs from PA exemption The General Assembly could consider removing PA exemptions on anti-anxiety drugs, antidepressants, antipsychotics, and cross-indicated drugs that constitute 31% (and rising) of the prescription drug budget at the time of this study. The AAAX drugs are gaining an increasing percentage of the prescription drug budget.
- Broaden class review scope to encompass "Classes Not Reviewed"

In sum, by limiting the number of preferred drugs within a therapeutic class, choosing less costly preferred drugs, adding supplemental rebates, removing the "AAAX" drugs from PA exemption, and/or broadening the scope of the drug class reviews to encompass the classes not reviewed, the potential for overall savings increases.



#### **CHAPTER 1**

Impact of PDL on Health Outcomes of Indiana Medicaid Recipients by Measuring Direct Costs: Physician, Laboratory, Emergency Room and Inpatient Hospital Expenditures

#### **Overview and Background**

Indiana Senate Enrolled Act No. 228 (SEA 228) of the 2002 General Assembly provided for the creation and implementation of a preferred drug list (PDL) under Indiana Medicaid with prior authorization for drugs not included on the PDL. The concept behind the preferred drug list program is to ensure that Indiana Medicaid recipients receive the most effective prescription drugs available at the best possible price.

Common opposition to PDL programs has been based upon unsubstantiated allegations that negative health consequences may occur due to changes in medication therapy. The Indiana legislature required the Indiana Office of Medicaid Policy and Planning (OMPP) to determine if the PDL program served its intent of promoting efficacious and safe drug therapy while minimizing the expenditure to the State.

OMPP requires ACS State Healthcare to conduct a study to analyze the Indiana preferred drug list program (PDL) to determine if the PDL results in a negative impact on the health outcomes of Medicaid recipients as well as any cost shifting to other health care providers, laboratory, emergency or hospital services.

This health outcomes study uses retrospective, paid claims data to evaluate recipient outcomes that may be related to implementation of the PDL program. Any changes in medical utilization or costs for those affected by the PDL program, relative to those not affected, would be indicators of a possible association between the PDL program and health outcomes.

#### Methods

Data

The data for this study were derived from the historical paid claims files from the Indiana Medicaid program stored on the Medstat Decision Support System database. Data extracts pulled and created by Medstat for the period of March 1, 2002 to June 30, 2003 were transmitted to ACS State Healthcare.

Inclusion and Exclusion Criteria

Inclusion Criteria for Therapeutic Classes of Drugs Studied



Therapeutic classes are <u>included</u> in medical analyses under the following conditions:

- Therapeutic classes with the greatest likelihood of having at least 99% of paid medical claims available for the 6-month period following implementation of the therapeutic class. When using administrative claims databases, the lag time between when a medical service is provided and the time at which a claim for a medical service is entered into the database varies and may be delayed, especially for dual eligible recipients (Medicaid and Medicare). Therefore, at the time medical data were extracted for this study in January 2004, only therapeutic classes implemented from August 2002 through December 2002 were considered for inclusion.
- Therapeutic classes with a relatively large market shift to preferred drugs after PDL program implementation. This criterion was defined as drugs with 95% or less preferred drug use prior to PDL program implementation.
- Therapeutic classes approved for use as long-term maintenance therapy for chronic illnesses. This maintenance therapy criterion allows for a sufficient number of recipients to have taken preferred or nonpreferred drugs for a long, continuous period of time. Long-term maintenance therapy increases the likelihood of detecting an association due to the PDL program and not due to extraneous, unrelated influences.

Therapeutic classes are excluded from analyses under the following conditions:

- Therapeutic classes in which greater than 95% of recipients used a preferred drug prior to the PDL implementation. These classes were excluded due to an insufficient number of recipients who switched from nonpreferred to prefer in order to detect a change in health status.
- Therapeutic classes approved for short-term therapy or with large seasonal fluctuations in usage (e.g., non-sedating antihistamines). It cannot be determined from prescription claims if a recipient terminated therapy due to decreased symptoms or because the PDL program limited access to the medication. Hence, it would be impossible to determine if medical expenditures are associated with taking or not taking the drugs; and in turn, to determine if taking the drugs for such a short time is associated with medical expenditures.



After applying the criteria to the therapeutic classes for the PDL, this study covered recipients receiving medications in the following seven therapeutic classes:

- ACE Inhibitors implemented September in 2002
- Alpha/Beta Blocker Antihypertensive Drugs implemented in October 2002 (Grouped with Calcium Channel Blockers & Loop Diuretics for analyses)
- Calcium Channel Blocker Antihypertensive Drugs implemented in October 2002 (Grouped with October 2002 Alpha/Beta Blocker for analyses)
- Loop Diuretics implemented in October 2002 (Grouped with October 2002 Antihypertensives above for data analyses)
- Platelet Aggregation Inhibitors implemented in October 2002
- Thiazolidinediones implemented in December 2002
- Triptans implemented in December 2002

Only therapeutic classes implemented from August 2002 through December 2002 contained enough post-implementation data to conduct analyses for study inclusion. This means any class implemented after December 2002 was not included. Therapeutic classes implemented during August 2002 through December 2002, but are **not included in this study**, including the reasoning for exclusion, are listed as follows:

#### Therapeutic classes containing 100% Preferred Drugs

Benign Prostatic Hypertropy Drugs Nasal Corticosteroids Fluoroquinolone Antibiotics Macrolide Antibiotics

#### Therapeutic classes containing less than 5% market share change

ACE Inhibitor/Calcium Channel Blocker Combination (>95% preferred)
Statins (> 95% preferred)
Inhaled Corticosteroids
Leukotriene Receptor Antagonists
Short-& Long-Acting Beta Agonists
Antiemetic/Antivertigo Drugs
Heparin/Related Preparations

#### Therapeutic classes with seasonal variation or short-term therapy usage

Non-Sedating Antihistamines Proton Pump Inhibitors Cephalosporins Antifungal Drugs

#### Inclusion criteria for recipients

• To be included in the analysis, the patient treatment episode had to have a minimum of 6-months of pre-treatment and 6-months of post-treatment data available for analysis. Recipients with gaps between paid claims in excess of 60 days were



excluded for the analysis due to the possibility of temporary loss of eligibility. By definition, recipients with 60-day gaps in paid prescription claims did not utilize Medicaid services for prescriptions and were classified as not having continuous therapy with a drug in one of the therapeutic classes studied. Although patients who may have been non-compliant with their therapy are important, the purpose of this study was to measure the effects of the PDL program. Care was given to our recipient study group to not bias the study with the effects of non-compliance mixed within.

- Recipients were selected for study if they were taking drugs in one of the above therapeutic classes and had at least two PDL-related claims in the three-month period prior to PDL implementation. Recipients of PDL medications were further categorized as Preferred Recipients if at least 80 percent of their PDL-related claims were for preferred drugs; they were Nonpreferred Recipients if at least 80 percent of their PDL-related claims were for nonpreferred drugs. If their usage was mixed not predominantly preferred or nonpreferred recipients were excluded from study.
- Recipients were categorized by what happened in the three-month period following PDL implementation. There were recipients who: (1) Changed from nonpreferred drugs to preferred, (2) Changed from preferred drugs to nonpreferred, (3) Did not change from a preferred agent, (4) Did not change from a nonpreferred agent, (5) Terminated nonpreferred therapy, and (6) Terminated preferred therapy. Again, recipients of a combination of preferred and nonpreferred drugs were excluded from the analysis after this categorization.
- Recipients selected for the study were further categorized. The cohorts of interest are:
  - a. Cohort 1: Recipients taking a nonpreferred medication for 6-months before implementation of the PDL list and switched to a preferred medication after PDL program implementation. These recipients were labeled the "Therapy Change Group."
  - b. Cohort 2: Recipients already taking preferred drugs 6-months both before and after PDL program implementation. These cohorts were the comparison group labeled the "No Change Group."
- To increase specificity and validity of the study, only medical expenditures associated with conditions related to the drug therapy were measured. This allows a more detailed, narrow scope of expenditures; ensuring that only the expenditures associated with changes in therapy are being included. For example, physician office, lab, or hospital expenditures associated with motor vehicle accidents or broken bones are unrelated to changes in antihypertensive therapy and therefore were not included in measuring expenditure changes between groups.

However, increased specificity and validity may reduce sample sizes within certain therapeutic classes sometimes resulting a trade-off of lower power. Specific sample



sizes, p-values, and observed power for each therapeutic class are reported with each therapeutic class and type of expenditure analyzed.

#### Medical Data Study Period

Analyses of the effects of PDL implementation on medical utilization and costs was limited to certain therapeutic groups where potential changes were most likely to have occurred as a result of PDL implementation. Study periods were 6-months prior to and 6-months after that specific therapeutic class' PDL implementation. The month of implementation was excluded in the medical analyses since most implementations occurred mid-month.

- ACE Inhibitors implemented in September 2002 Study Period: 3/1/02 to 3/31/03
- Alpha/Beta Adrenergic Blocker Hypertensives implemented in October 2002 Study Period: 4/1/02 to 4/30/03
- Calcium Channel Blocker Hypertensives implemented in October 2002 Study Period: 4/1/02 to 4/30/03
- Loop Diuretics implemented in October 2002 Study Period: 4/1/02 to 4/30/03
- Platelet Aggregation Inhibitors implemented in October 2002 Study Period: 4/1/02 to 4/30/03
- Thiazolidinediones implemented in December 2002 Study Period: 6/1/02 to 6/30/03
- Triptans implemented in December 2002 Study Period: 6/1/02 to 6/30/03

#### Specification of Recipient Outcome Measures

Selected outcomes measures studied are expenditures for physician office visits, emergency room services, laboratory services, and inpatient hospital admissions. Medical outcomes are evaluated 6-months before and after implementation month for each of the two groups of recipients per therapeutic class studied. The month of PDL implementation for the associated therapeutic class was assigned a null period in which no measurements were taken.

#### Outcome Measure Definitions

Only services related to the disease states treated with the therapeutic class being studied are used in calculating medical expenditures for each service type. This allows a more detailed, narrow scope of expenditures; ensuring that only the expenditures associated with changes in therapy are being included. For example, physician office, lab, or hospital expenditures associated with motor vehicle accidents or broken bones are unrelated to changes in antihypertensive therapy and therefore were not included in measuring expenditure changes between groups.



Inpatient hospital services were measured as a count of each admission date per recipient ID and all expenditures associated with each unique recipient ID per admission date on the inpatient UB-92 claims. Inpatient hospital expenditures were measured only for services related to the disease state associated with the therapeutic class being studied. For example, when analyzing ACE Inhibitors and Antihypertensives, only the DRG codes for cardiovascular services were measured (see Table 1.1). For thiazolidinediones, expenditures associated with the specific DRG codes for cardiovascular, endocrine, and kidneys were used.

Physician office visits were defined by detail procedure codes associated with outpatient or office services involving physician evaluation and management of patients (shown in Table 1.1).

Table 1.1 Procedure Codes & DRG Codes Used to Define Specific Types of Medical Services Studied

TVICUICAI DEI VIC	ees studied	
Service Types	Detail Procedure Codes	DRG Codes
Physician Office or Outpatient	99201-99215	
Visits	99241-99245	N/A
	99354-99357	
	99361-99380	
Laboratory Services	80000 – 89999	N/A
•	95250 – glucose monitoring	
Emergency Physician Services	99281-99288	N/A
Services Related to:		N/A
End-Stage Renal Disease &	90918- 90999	302-333
Dialysis		
Cardiovascular	92950 – 93981 (includes	103-145;
	extremity arterial & venous	478,479,514-518;
	studies)	525-527
Endocrine		285-301
Pulmonary	94010 - 94799	N/A
Gastroenterology	91000-91299	N/A
Ophthalmology	92002 - 92499	N/A
Allergy & Clinical	95004 – 95199	N/A
Immunology		

Laboratory services are defined by detail procedure codes in the range: 80000-89999 and 95250 (glucose monitoring). Emergency services are defined by locating the emergency physician services by procedure codes 99281-99288, and then rolling up the costs of all detail numbers associated with those emergency services claims.



#### **Cost Definition**

To explore the impact of drug use patterns associated with the PDL program on direct medical costs, Indiana Medicaid claims were partitioned by type of service. The amount actually paid directly by the Indiana Medicaid program minus recipient co-pays and other insurance was used as the Amount Paid for expenditures. We acknowledge that this definition does not capture the full costs of medical expenditures since Medicare is the primary payer for Medicare covered services and Indiana Medicaid would pay only the balance. However, this study is only measuring differences in paid amounts between two groups. Since we are only interested in payment <u>changes</u> between groups, we contend that amount paid is sufficient because it applies equally to both groups.

#### Method of Analysis

Comparison of mean expenditures was conducted for each therapeutic class by using univariate analysis of variance (ANOVA) for outpatient data. Multiple comparisons ANOVA (MANOVA) was of benefit for analyses of inpatient hospital expenditures for all seven therapeutic classes.

The issue explored was whether recipients affected by the PDL (i.e., those whose medications were changed from nonpreferred to preferred drugs) showed significant mean differences in expenditures compared to those not affected by the PDL (i.e. those who had no change in their medication). If any changes were observed, post hoc analyses were conducted to determine which group had greater expenditures. Comparing mean expenditures between groups is one way to estimate if there were any detrimental effects to the health of recipients associated with the PDL program. If detrimental effects occurred, patients could require greater medical expenditures from increased physician visits, hospitalizations, and lab monitoring procedures.

#### Specific cohorts are defined as:

- 1. Cohort 1 (Therapy Change Group): Recipients taking a nonpreferred medication for 6-months before implementation of the PDL list and switched to a preferred medication after PDL program implementation.
- 2. Cohort 2 (No Change Group): Recipients already taking preferred drugs 6-months both before and after PDL program implementation. These cohorts were the comparison group labeled the "No Change Group."

Comparisons of mean expenditures for each cohort group were conducted by medical service type, pre- and post-PDL program periods over all seven therapeutic classes and for each therapeutic class.



#### Results

ACE Inhibitors (Implemented September, 2002)

For recipients taking ACE inhibitors, no statistically significant differences were observed in the overall medical expenditures and in specific medical service types between the two groups (recipients affected by the PDL program versus recipients not affected) except for laboratory expenditures in the ACE inhibitors (p=0.002).

Table 1.2 ACE Inhibitors – General Linear Model – ANOVA

(Tests of Between Subjects Effects & Descriptive Statistics)

	Change			Std.			Observed
Outcomes	History	Time Period	Mean	Deviation	N	Sig.	Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$63.79	\$106.90	3802		
		6-mo Post-PDL Implementation	\$47.05	\$91.39	3802		
MD Office		Total	\$55.42	\$99.79	7604	.851	.028
Expenditures	Therapy Change:	6-mo Pre-PDL Implementation	\$61.44	\$102.09	4926		
	Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$45.26	\$90.00	4926		
		Total	\$53.35	\$96.61	9852		
	Total	6-mo Pre-PDL Implementation	\$62.46	\$104.21	8728		
		6-mo Post-PDL Implementation	\$46.04	\$90.66	8728		
		Total	\$54.25	\$98.01	17456		
	No Change	6-mo Pre-PDL Implementation	\$16.57	\$57.68	3802		
		6-mo Post-PDL Implementation	\$12.72	\$47.78	3802		
Emergency		Total	\$14.64	\$52.99	7604	.936	.025
Dept Expenditures	Therapy Change:	6-mo Pre-PDL Implementation	\$15.52	\$55.82	4926	.930	.023
	Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$11.80	\$52.33	4926		
		Total	\$13.66	\$54.13	9852		
	Total	6-mo Pre-PDL Implementation	\$15.97	\$56.64	8728		
		6-mo Post-PDL Implementation	\$12.20	\$50.40	8728		
		Total	\$14.09	\$53.64	17456		
	No Change	6-mo Pre-PDL Implementation	\$42.77	\$167.23	3802		
		6-mo Post-PDL Implementation	\$32.12	\$91.62	3802		
Laboratory Services		Total	\$37.44	\$134.93	7604	.002	.813
Expenditures	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$15.34	\$59.66	4926		
	Preferred	6-mo Post-PDL Implementation	\$14.14	\$54.44	4926		
		Total	\$14.74	\$57.11	9852		
	Total	6-mo Pre-PDL Implementation	\$27.29	\$119.89	8728		
		6-mo Post-PDL Implementation	\$21.97	\$73.54	8728		
	-1	Total	\$24.63	\$99.49	17456		

a. Computed using alpha = .025



**Table 1.2ACE Inhibitors – CONTINUED –** 

Outcomes	Change History	Time Period	Mean	Std. Deviation	N	Sig.	Observed Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$82.31	\$431.82	3802		
Other Outpatient	140 Change	6-mo Post-PDL Implementation	\$72.10	\$422.70	3802		
Costs Related		Total	\$77.21	\$427.29	7604	.513	.058
to Disease	Therapy Change:	6-mo Pre-PDL Implementation	\$36.98	\$249.16	4926	.513	.058
	Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$33.38	\$208.49	4926		
		Total	\$35.18	\$229.72	9852		
	Total	6-mo Pre-PDL Implementation	\$56.73	\$341.70	8728		
		6-mo Post-PDL Implementation	\$50.25	\$320.50	8728		
		Total	\$53.49	\$331.27	17456		
	No Change	6-mo Pre-PDL Implementation	\$205.45	\$557.96	3802		
Total Medical		6-mo Post-PDL Implementation	\$164.01	\$500.60	3802		
Expenditures		Total	\$184.73	\$530.42	7604	400	477
	Therapy Change: Nonpreferred to Preferred	6-mo Pre-PDL Implementation	\$129.29	\$324.81	4926	.189	.177
	Treiched	6-mo Post-PDL Implementation	\$104.60	\$280.90	4926		
		Total	\$116.94	\$303.89	9852		
	Total	6-mo Pre-PDL Implementation	\$162.47	\$443.35	8728		
		6-mo Post-PDL Implementation	\$130.48	\$393.12	8728		
		Total	\$146.47	\$419.28	17456		

a. Computed using alpha = .025



Antihypertensives (Implemented October 2002)

In recipients taking Alpha/Beta Blocker Antihypertensives, Calcium Channel Blocker Antihypertensives, and Loop Diuretics, no statistically significant differences were observed in the overall medical expenditures and in specific medical service types between the two groups (recipients affected by the PDL program versus recipients not affected).

Table 1.3 Therapeutic Classes on PDL in October 2002 Alpha/Beta Blocker Antihypertensives, Calcium Channel Blocker Antihypertensives & Loop Diuretics – General Linear Model –ANOVA

(Tests of Between Subjects Effects & Descriptive Statistics)

Outcomes	Change History	Time Period	Mean	Std. Deviation	N	Sig.	Observed Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$54.76	\$97.99	2,852		
MD Office		6-mo Post-PDL Implementation	\$43.61	\$90.19	2,852		
Expenditures		Total	\$49.19	\$94.33	5,704	.419	.077
	Therapy	6-mo Pre-PDL Implementation	\$38.76	\$70.87	250		
	Change: Nonpreferred to	6-mo Post-PDL Implementation	\$34.60	\$75.43	250		
	Preferred	Total	\$36.68	\$73.14	500		
		6-mo Pre-PDL Implementation	\$53.47	\$96.18	3,102		
	Total	6-mo Post-PDL Implementation	\$42.89	\$89.11	3,102		
		Total	\$48.18	\$92.86	6,204		
	No Change	6-mo Pre-PDL Implementation	\$15.39	\$56.68	2,852		
Emergency		6-mo Post-PDL Implementation	\$13.61	\$54.61	2,852		
Dept		Total	\$14.50	\$55.66	5,704	.718	025
Expenditures	Therapy	6-mo Pre-PDL Implementation	\$12.27	\$40.32	250	./10	.035
	Change: Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$12.35	\$60.14	250		
	Preierred	Total	\$12.31	\$51.15	500		
		6-mo Pre-PDL Implementation	\$15.14	\$55.54	3,102		
	Total	6-mo Post-PDL Implementation	\$13.50	\$55.06	3,102		
		Total	\$14.32	\$55.31	6,204		
	No Change	6-mo Pre-PDL Implementation	\$36.59	\$135.91	2,852		
Laboratory		6-mo Post-PDL Implementation	\$29.59	\$115.82	2,852		
Services		Total	\$33.09	\$126.30	5,704	.200	.168
Expenditures	Therapy	6-mo Pre-PDL Implementation	\$26.79	\$94.65	250	.200	.100
	Change: Nonpreferred to	6-mo Post-PDL Implementation	\$34.85	\$148.21	250		
	Preferred	Total	\$30.82	\$124.29	500		
		6-mo Pre-PDL Implementation	\$35.80	\$133.07	3,102		
Total	Total	6-mo Post-PDL Implementation	\$30.01	\$118.74	3,102		
		Total	\$32.90	\$126.13	6,204		

a Computed using alpha = .025



#### Table 1.3 continued -- Therapeutic Classes on PDL in October 2002

Alpha/Beta Blocker Antihypertensives, Calcium Channel Blocker Antihypertensives & Loop Diuretics

		L Loop Dia		Std.			Observed
Outcomes	Change History	Time Period	Mean	Deviation	N	Sig.	Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$87.27	\$993.85	2,852		_
Other Office/ Outpatient Costs		6-mo Post-PDL Implementation	\$78.57	\$650.98	2,852		
Related to		Total	\$82.92	\$840.03	5,704		
Disease	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$72.38	\$675.29	250	.952	.025
	Preferred	6-mo Post-PDL Implementation	\$68.30	\$627.03	250		
		Total	\$70.34	\$650.96	500		
	Total	6-mo Pre-PDL Implementation	\$86.07	\$971.98	3,102		
		6-mo Post-PDL Implementation	\$77.74	\$648.99	3,102		
		Total	\$81.91	\$826.36	6,204		
	No Change	6-mo Pre-PDL Implementation	\$194.01	\$1,053.10	2,852		
Total Outpatient Medical	- Tro Gridings	6-mo Post-PDL Implementation	\$165.37	\$721.98	2,852		
Expenditures		Total	\$179.69	\$902.89	5,704	.731	.034
	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$150.20	\$745.40	250		
	Preferred	6-mo Post-PDL Implementation	\$150.11	\$708.29	250		
		Total	\$150.16	\$726.35	500		
	Total	6-mo Pre-PDL Implementation	\$190.48	\$1,031.69	3,102		
		6-mo Post-PDL Implementation	\$164.14	\$720.78	3,102		
		Total	\$177.31	\$889.94	6,204		

a Computed using alpha = .025



Platelet Aggregation Inhibitors (Implemented October 2002)

In recipients taking Platelet Aggregation Inhibitors, those switched from nonpreferred to preferred drugs did not exhibit any statistically significant differences in overall medical expenditures from recipients who were already taking a preferred agent. There was a statistically significant difference in physician office expenditures between recipients who switched and those who remained on preferred agents for platelet aggregation inhibitors only (p=0.001).

Table 1.4 Platelet Aggregation Inhibitors -- General Linear Model - Tests of

**Between-Subjects Effects & Descriptive Statistics** 

Outcomes	Change History	Time Period	Mean	Std. Deviation	N	Sig.	Observed Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$.59	\$4.62141	3166		
		6-mo Post-PDL Implementation	\$.77	\$6.77589	3166		
		Total	\$.68	\$5.79983	6332	004	044
MD Office	Therapy Change:	6-mo Pre-PDL Implementation	\$4.09	\$54.90017	219	.001	.841
Expenditures	Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$.63	\$5.58778	219		
		Total	\$2.36	\$39.01466	438		
	Total	6-mo Pre-PDL Implementation	\$.81	\$14.65897	3385		
		6-mo Post-PDL Implementation	\$.76	\$6.70477	3385		
		Total	\$.79	\$11.39742	6770		
	No Change	6-mo Pre-PDL Implementation	\$3.52	\$30.62451	3166		
		6-mo Post-PDL Implementation	\$1.42	\$7.80498	3166		
<b>-</b>		Total	\$2.47	\$22.36985	6332		
Emergency Dept	Therapy Change:	6-mo Pre-PDL Implementation	\$2.83	\$10.53810	219	.974	.025
Expenditures	Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$.66	\$3.41851	219	.974	.023
		Total	\$1.74	\$7.89974	438		
	Total	6-mo Pre-PDL Implementation	\$3.47	\$29.73801	3385		
		6-mo Post-PDL Implementation	\$1.37	\$7.60024	3385		
		Total	\$2.42	\$21.72766	6770		
	No Change	6-mo Pre-PDL Implementation	\$26.60	\$113.9054	3166		
Laboratory Services		6-mo Post-PDL Implementation	\$12.39	\$57.71987	3166		
Expenditures		Total	\$19.50	\$90.56609	6332		
	Therapy Change:	6-mo Pre-PDL Implementation	\$14.16	\$79.85387	219	.273	.126
	Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$9.62	\$67.92201	219	.213	.120
		Total	\$11.89	\$74.07838	438		
	Total	6-mo Pre-PDL Implementation	\$25.80	\$112.0488	3385		
		6-mo Post-PDL Implementation	\$12.21	\$58.42636	3385		
		Total	\$19.00	\$89.60611	6770		

a Computed using alpha = .025



**Table 1.4** ---CONTINUED -Platelet Aggregation Inhibitors -- GLM Analysis

Outcomes	Change History	Time Period	Mean	Std. Deviation	N	Sig.	Observed Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$73.91	\$486.76	3166		
		6-mo Post-PDL Implementation	\$36.97	\$299.07	3166		
Other Office/Outpatient		Total	\$55.44	\$404.36	6332		
Costs Related to Disease	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$13.81	\$131.28	219	.329	.104
Disease	Preferred	6-mo Post-PDL Implementation	\$14.70	\$122.03	219	.020	.104
		Total	\$14.25	\$126.60	438		
	Total	6-mo Pre-PDL Implementation	\$70.02	\$472.15	3385		
		6-mo Post-PDL Implementation	\$35.53	\$290.94	3385		
		Total	\$52.78	\$392.51	6770		
	No Change	6-mo Pre-PDL Implementation	\$104.63	\$524.87	3166		
Total Outpatient		6-mo Post-PDL Implementation	\$51.57	\$326.17	3166		
Medical .		Total	\$78.10	\$437.74	6332		
Expenditures	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$34.90	\$169.37	219	.297	.116
	Preferred	6-mo Post-PDL Implementation	\$25.62	\$159.78	219		
		Total	\$30.26	\$164.52	438		
	Total	6-mo Pre-PDL Implementation	\$100.12	\$509.71	3385		
		6-mo Post-PDL Implementation	\$49.89	\$318.09	3385		
		Total	\$75.00	\$425.56	6770		

a Computed using alpha = .025



Thiazolidinediones (Implemented December 2002)

In recipients taking thiazolidinediones, no statistically significant differences were observed in the overall medical expenditures and in specific medical service types between the two groups (recipients affected by the PDL program versus recipients not affected).

**Table 1.5 Thiazolidinediones – General Linear Model - Tests of Between-Subjects** 

**Effects & Descriptive Statistics** 

Outcomes	Change History	Time Period	Mean	Std. Deviation	N	Sig.	Observed Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$61.40	\$108.61	1835		
MD Office Expenditures		6-mo Post-PDL Implementation	\$58.02	\$97.65	1835	.305	.113
		Total	\$59.71	\$103.28	3670		
	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$61.40	\$108.36	1742		
	Preferred	6-mo Post-PDL Implementation	\$63.16	\$108.50	1742		
		Total	\$62.28	\$108.42	3484		
	Total	6-mo Pre-PDL Implementation	\$61.40	\$108.47	3577		
		6-mo Post-PDL Implementation	\$60.52	\$103.09	3577		
		Total	\$60.96	\$105.81	7154		
	No Change	6-mo Pre-PDL Implementation	\$18.50	\$67.40	1835		
Emergency Dept		6-mo Post-PDL Implementation	\$16.34	\$57.90	1835	.707	.035
Expenditures		Total	\$17.42	\$62.83	3670		
	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$16.68	\$57.37	1742		
	Preferred	6-mo Post-PDL Implementation	\$15.57	\$51.67	1742		
		Total	\$16.12	\$54.59	3484		
	Total	6-mo Pre-PDL Implementation	\$17.61	\$62.72	3577		
		6-mo Post-PDL Implementation	\$15.96	\$54.95	3577		
		Total	\$16.79	\$58.96	7154		

a Computed using alpha = .025



Table 1.5 -- CONTINUED - Thiazolidinediones -- General Linear Model - Tests of Between-Subjects Effects & Descriptive Statistics

Outcomes	Change History	Time Period	Mean	Std. Deviation	N	Sig.	Observed Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$44.64	\$103.33	1835		
Laboratory Services		6-mo Post-PDL Implementation	\$43.39	\$105.59	1835		
Expenditures		Total	\$44.01	\$104.45	3670		
	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$44.21	\$99.21	1742	.935	.025
	Preferred	6-mo Post-PDL Implementation	\$43.36	\$105.74	1742		
		Total	\$43.79	\$102.52	3484		
	Total	6-mo Pre-PDL Implementation	\$44.43	\$101.33	3577		
		6-mo Post-PDL Implementation	\$43.38	\$105.65	3577		
		Total	\$43.90	\$103.51	7154		
Other	No Change	6-mo Pre-PDL Implementation	\$96.48	\$579.01	1835		
Office/Outpatie nt Costs		6-mo Post-PDL Implementation	\$78.49	\$462.47	1835		
Related to		Total	\$87.48	\$523.99	3670		
Disease	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$76.24	\$316.67	1742	.898	.026
	Preferred	6-mo Post-PDL Implementation	\$55.65	\$266.13	1742		
		Total	\$65.94	\$292.63	3484		
	Total	6-mo Pre-PDL Implementation	\$86.62	\$469.96	3577		
		6-mo Post-PDL Implementation	\$67.37	\$379.87	3577		
		Total	\$76.99	\$427.37	7154		
	No Change	6-mo Pre-PDL Implementation	\$221.03	\$678.10	1835		
Total Outpatient		6-mo Post-PDL Implementation	\$196.24	\$544.22	1835		
Medical Expenditures		Total	\$208.64	\$614.86	3670		
Experialitates	Therapy Change:	6-mo Pre-PDL Implementation	\$198.55	\$424.59	1742	.872	.027
	Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$177.75	\$391.50	1742		
		Total	\$188.15	\$408.46	3484		
	Total	6-mo Pre-PDL Implementation	\$210.08	\$568.96	3577		
		6-mo Post-PDL Implementation	\$187.24	\$476.03	3577		
		Total	\$198.66	\$524.65	7154		

a Computed using alpha = .025



Triptans (Implemented December, 2002)

In recipients taking Triptans, no statistically significant differences were observed in the overall medical expenditures and in specific medical service types between the two groups (recipients affected by the PDL program versus recipients not affected).

Table 1.6 Triptans – General Linear Model - Tests of Between-Subjects Effects &

**Descriptive Statistics** 

Outcomes	Change History	Time Period	Mean	Std. Deviation	N	Sig.	Observed Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$131.52	\$164.26	507		
MD Office		6-mo Post-PDL Implementation	\$119.52	\$158.57	507		
Expenditures		Total	\$125.52	\$161.47	1014		
Therapy Change Nonpreferred to Preferred	Therapy Change:	6-mo Pre-PDL Implementation	\$155.47	\$159.82	63	.867	.027
	6-mo Post-PDL Implementation	\$148.55	\$149.37	63			
		Total	\$152.01	\$154.11	126		
	Total	6-mo Pre-PDL Implementation	\$134.17	\$163.811	570		
		6-mo Post-PDL Implementation	\$122.73	\$157.72	570		
		Total	\$128.45	\$160.83	1140		
-	No Change	6-mo Pre-PDL Implementation	\$48.93	\$110.80	507		
Emergency		6-mo Post-PDL Implementation	\$45.95	\$99.70	507		
Dept		Total	\$47.44	\$105.35	1014		
Expenditures	Therapy Change: Nonpreferred to	6-mo Pre-PDL Implementation	\$74.55	\$154.349	63		
	Preferred	6-mo Post-PDL Implementation	\$43.35	\$77.62	63	.164	.197
		Total	\$58.95	\$122.68	126		
	Total	6-mo Pre-PDL Implementation	\$51.76	\$116.52	570		
		6-mo Post-PDL Implementation	\$45.66	\$97.45	570		
		Total	\$48.71	\$107.41	1140		

a Computed using alpha = .025



---CONTINUED --Triptans (December 2002 PDL)

**Table 1.6** continued -- **General Linear Model - Tests of Between-Subjects Effects & Descriptive Statistics - Triptans** 

Outcomes	Change History	Time Period	Mean	Std. Deviation	N	Sig.	Observed Power <sup>a</sup>
	No Change	6-mo Pre-PDL Implementation	\$60.3906	\$110.80566	507		
Laboratory Services		6-mo Post-PDL Implementation	\$59.1308	\$117.84022	507		
Expenditures		Total	\$59.7607	\$114.32230	1014	.619	.044
	Therapy Change:	6-mo Pre-PDL Implementation	\$73.0997	\$129.94674	63	.0.0	
	Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$82.8829	\$152.07871	63		
		Total	\$77.9913	\$140.96492	126		
	Total	6-mo Pre-PDL Implementation	\$61.7953	\$113.02368	570		
		6-mo Post-PDL Implementation	\$61.7560	\$122.16574	570		
		Total	\$61.7756	\$117.63185	1140		
Other Office/	No Change	6-mo Pre-PDL Implementation	\$38.9847	\$216.77987	507		
		6-mo Post-PDL Implementation	\$37.6670	\$160.09065	507		
Outpatient		Total	\$38.3258	\$190.46221	1014	.280	.123
Costs Related to Disease	Therapy Change: Nonpreferred to Preferred	6-mo Pre-PDL Implementation	\$59.9629	\$213.78210	63		
		6-mo Post-PDL Implementation	\$20.4133	\$58.34019	63		
		Total	\$40.1881	\$157.32427	126		
	Total	6-mo Pre-PDL Implementation	\$41.3034	\$216.36456	570		
		6-mo Post-PDL Implementation	\$35.7600	\$152.28768	570		
		Total	\$38.5317	\$187.02818	1140		
	No Change	6-mo Pre-PDL Implementation	\$279.830 6	\$407.60435	507		
Total		6-mo Post-PDL Implementation	\$262.27	\$381.22061	507		
Outpatient		Total	\$271.05	\$394.53597	1014	.501	.060
Medical Expenditures	Therapy Change:	6-mo Pre-PDL Implementation	\$363.09	\$474.78051	63		
	Nonpreferred to Preferred	6-mo Post-PDL Implementation	\$295.20	\$317.45563	63		
		Total	\$329.14	\$403.67562	126		
	Total	6-mo Pre-PDL Implementation	\$289.03	\$415.92171	570	_	
		6-mo Post-PDL Implementation	\$265.91	\$374.60126	570		
		Total	\$277.47	\$395.79628	1140		

a Computed using alpha = .025



Inpatient Hospital Data for All Therapeutic Classes

Of the therapeutic drug classes evaluated, no statistically significant differences were observed in the inpatient hospital expenditures

Table 1.7 Inpatient Hospital Amount Paid Total by All Six Therapeutic Classes

Dependent Variable: Total Inpatient Amount Paid

Dependent Variabl	Time			Std.		Sig	Observ
Change History	Period	Therapeutic Class	Mean	Std. Deviation	N		ed Power <sup>a</sup>
Onlange motory	6-months	ACE Inhibitors	\$168.97	\$1,429.84	3,802		1 01101
	Pre-PDL	Alpha/Beta/ CaCh Block Antihyp & Loop Diuretics	\$138.46	\$1,177.18	2,852		
No Change: Preferred Stay		Thiazolidinediones	\$162.71	\$1,122.79	1,835		
Pref		Triptans	\$35.58	\$299.56	507		
		Platelet Agg Inhibitors	\$206.00	\$1,405.71	3,166		
		Total	\$164.95	\$1,293.57	12,162		
	6-months	ACE Inhibitors	\$84.90	\$847.26	3,802		
	POST- PDL	Alpha/Beta CaCh Block Antihyp & Loop Diuretics	\$112.15	\$917.55	2,852		
		Thiazolidinediones	\$118.25	\$888.82	1,835		
		Triptans	\$71.18	\$644.35	507		
		Platelet Agg Inhibitors	\$80.84	\$798.92	3,166		
		Total	\$94.69	\$851.20	12,162		
	Total	ACE Inhibitors	\$126.93	\$1,175.90	7,604	.372	.243
		Alpha/Beta CaCh Block Antihyp & Loop Diuretics	\$125.31	\$1,055.37	5,704		
		Thiazolidinediones	\$140.48	\$1,012.69	3,670		
		Triptans	\$53.38	\$502.52	1,014		
		Platelet Agg Inhibitors	\$143.42	\$1,144.93	6,332		
		Total	\$129.82	\$1,095.49	24,324		
	6-months	ACE Inhibitors	\$108.43	\$974.80	4,926		
	Pre-PDL	Alpha/Beta CaCh Block Antihyp & Loop Diuretics	\$85.98	\$540.46	250		
Change:		Thiazolidinediones	\$139.90	\$1,038.05	1,742		
NonPreferred to Pref		Triptans	\$144.68	\$1,148.37	63		
FIEI		Platelet Agg Inhibitors	\$27.51	\$216.12	219		
		Total	\$113.12	\$966.44	7,200		
	6-months	ACE Inhibitors	\$123.03	\$1,099.87	4,926		
	POST- PDL	Alpha/Beta CaCh Block Antihyp & Loop Diuretics	\$113.03	\$737.98	250		
		Thiazolidinediones	\$98.58	\$789.99	1,742		
		Triptans	\$1.74	\$13.83	63		
		Platelet Agg Inhibitors	\$5.05	\$59.48	219		
		Total	\$112.12	\$999.02	7,200		
	Total	ACE Inhibitors	\$115.73	\$1,039.19	9,852		
		Alpha/Beta Block CaCh Antihyp & Loop Diuretics	\$99.51	\$646.30	500		
		Thiazolidinediones	\$119.24	\$922.50	3,484		
		Triptans	\$73.21	\$812.00	126		
		Platelet Agg Inhibitors	\$16.28	\$158.72	438		
		Total	\$112.62	\$982.83	14,400		

a Computed using alpha = .025



#### Conclusion

The Indiana DUR Board and OMPP have demonstrated a commitment to addressing the health care needs of its Medicaid population. OMPP is committed to providing quality health care, while maximizing the financial resources available. The PDL program was implemented to ensure the quality of care and minimize the expenditures to the State of Indiana, while minimizing the impact to recipients and health care providers. As a consequence, OMPP is required to analyze the impact of the PDL program and identify any unintended consequences associated with the PDL program.

In the 7 therapeutic drug classes and 38,724 recipients evaluated over both a 6-month pre- and post-implementation of the PDL program, the evidence does not suggest that recipients affected by the PDL (by requiring a change to a preferred medication) have higher overall medical costs as a result. Recipients impacted by the PDL program do not demonstrate a statistically significant increase in overall medical expenditures when compared to recipients not affected by the PDL program.

#### **Discussion and Limitations**

Caution must be used in the interpretation of these results. The following limitations should be noted when evaluating the findings of this section.

Retrospective studies, such as this one, are subject to numerous biases. Since it is impractical to operate a Medicaid program like a controlled clinical trial, there may be differences observed in user groups that are not necessarily attributable to the program itself but to other confounding factors that are difficult to control for or are unknown. For this reason, results of retrospective observational studies such as this one are considered associations and not causal.

Furthermore, the type of statistical tests performed can help account for biases known to be a part of the analyses. The between-group variances were significantly different; meaning, one of the assumptions of ANOVA were violated. Yet, ANOVA is known for being a very robust test. A repeated measures analysis was conducted due to its design advantage in reducing the unsystematic variability in the design and so provides greater power to detect effects. Further analyses using the Bonferroni method were performed to verify results. The Bonferroni method has been shown to be extremely robust and controlled alpha levels and Type 1 error rates best of all the univariate techniques.

Levine's test of equality of error variances was significant for many therapeutic classes and service types, meaning the between-group variances are significantly different. Levine's test of equality of error variances was most often significant for emergency room services, laboratory, and inpatient hospital services where number of incidences and sample size are low. When sample sizes are low, some recipients in this study may have measurements much different from the average user (outliers) and thus can "skew" the results. However, the tests used to analyze the data in this study are "robust" as to limit the effect of "skewed" data.



Since Levine's test was significant in some medical, then steps should be taken in future studies to equalize the variances through data transformation such as taking the square root of, rate of change of all values of the dependent variable, or removing outliers prior to analyses. Data transformation is recommended for future follow-up studies.

There is an apparent selection bias inherent in the two cohorts studied. This means that there are systematic differences in the groups studied based on the way the recipients were selected into the study groups. For example, in some therapeutic classes (or disease states), recipients who were already taking the preferred drugs were stabilized and were inherently using less medical resources both pre- and post-PDL implementation than those in the nonpreferred groups. It would make sense that users of a medication that a therapeutics committee deemed to be clinically superior would have different health outcomes than those who used a "nonpreferred" potentially inferior medication, then switched to the "preferred" medication. Conversely, in some therapeutic classes where the medications were equally effective, recipients switched from a newer, more expensive "nonpreferred" medication may not be as sick as a recipient who has been taking an older, less expensive "preferred" medication for a long time. Thus, the results observed from each therapeutic class studied may not apply to other therapeutic classes.

The medical analyses in this study are based on the paid amounts by the State of Indiana Medicaid Program. Paid amounts (expenditures that the state incurred) are only one measure of costs of providing services. Fluctuations in third party liability (TPL) expenditures and co-pays are not accounted for when using paid amounts. There is also the possibility of missing services performed that have not yet been filed or paid. For these reasons, this study does not capture trends in the total overall expenditures for medical services but rather the State's liability for the services studied.

The 6-month post-PDL study period is a relatively short-term follow-up. Medical illnesses may take longer than 6 months to develop and further follow-up with longer post-periods should be conducted. Any effects of the program may become more evident during subsequent biannual PDL evaluations. We will be conducting on-going analysis of impact on medical expenditures and add to the study as we collect data.

#### **Future Directions**

This analysis is a good start toward the ongoing analysis of effects of the PDL program upon medical costs of recipients affected by the program (Chapter 1). The two largest limitations to the current study, low power measures in many of the drug classes studied and highly skewed medical data, should be rectified in future iterations of this study. Attempts should be made to normalize the highly skewed health care cost data through, for example, log transformation. Additionally, it is likely that study of a longer time frame will increase the number of recipients with medical data and power analyses may move toward more confidence in the statistical results.



# CHAPTER 2 The Effects of the Preferred Drug List Program on Medicaid Recipients' Access to Medications

#### Abstract

This analysis was performed to determine if the implementation of the Indiana State Medicaid Preferred Drug List (PDL) Program impacted medication access for participants. The study covered therapeutic classes subject to the PDL for claims processed between May and September 2003. Specifically, 3 groups of therapeutic classes were evaluated; (1) Those subjected to the preferred drug list implemented in May 2003; (2) Those with the preferred drug list implemented in July 2003; and (3) a group of related therapeutic classes used to control hypertension that were implemented on various dates between September 2002 and January 2003. Combining all groups, we evaluated an average of 188,508 recipients per month who were using medications subject to the PDL. During this period, only 4462 (2.3%) experienced a denied pharmacy claim. Most of these recipients went on to receive the medication through a prior authorization approval. Over half of the follow-up claims were processed on the same day that the denial occurred. Of the 188,508 monthly recipients followed, only 1485 (0.78%) experienced a denied claim with no paid claim for a related medication within 30 days. Further, denials for a given class diminished monthly as providers gained experience with the program. It is impossible to know from pharmacy claims data what portion of these dropped claims were duplicate or unnecessary therapies. Overall, this number suggests a minimum impact on PDL users.

#### Introduction

This chapter explores the impact of the Indiana Preferred Drug List program on access to medications. It is desirable to increase the share of "preferred" medications versus "nonpreferred" medications while generating few denied claims. When claims are denied, it is important to enable participants who need prescribed medications to obtain them while limiting inappropriate use of medications. This analysis attempts to quantify the number of participants subject to the PDL in a specific time period that have denied claims and whether the medication, or a related medication, is subsequently obtained by the recipient.

Under a PDL program, claims for nonpreferred medications cause a denial edit to post on the dispensing pharmacy's point of service response. This edit directs the pharmacist to contact the dispensing physician, who either instructs the dispensing pharmacist to dispense a "preferred medication," calls an ACS consulting pharmacist to discuss alternative therapy, or requests prior approval for use of the originally prescribed "nonpreferred" medication. Claim denials may also occur if there is an attempt to refill a prescription too early. The prescriber may discuss any of these events with the reviewing



pharmacist to arrive at an appropriate course of action. The possible outcomes of denied claim events are 1) the new prescription is filled without delay, 2) the new prescription is filled after a delay, or 3) no related follow-up prescription is prescribed. Not all delays or therapy terminations associated with a PDL program are undesirable. Delays can occur between the time of the denial and the next fill because the participant attempted to receive an early refill. The physician might not have chosen to call for a prior authorization and simply allowed the therapy to terminate. There might have been no follow up prescription filled because the member was no longer eligible for Medicaid, or because the prescription was no longer necessary. Lastly, the physician may have given the recipient prescription samples during their office visit with the physician. Although a delay in the payment for a claim is quantifiable, it is difficult to truly quantify an actual delay in therapy from claims data. A pharmacist may choose to dispense a small supply of a denied medication for a recipient until such time that the prescribing physician requests a prior authorization for the product.

This analysis examined three groups of therapeutic classes (as identified in Table 2.1): (1) Those subjected to the preferred drug list implemented in May 2003; (2) Those with a preferred drug list implemented in July 2003; and (3) a group of related therapeutic classes used to control hypertension that were implemented on various dates between September 2002 and January 2003. The study covered claims for medications in those classes processed between May and September 2003.

Within each group studied, there was considerable variation across the classes in the degree to which participants were affected, reflecting differing clinical attributes of the medications involved and the small number of affected recipients for some classes. In addition, there was some variation across the groups, reflecting maturation of the program in classes implemented earlier. The classes with the longest history of operation tended to have lower proportions of participants with denied claims.

Since the only data available to perform this analysis consisted of drug claims and prior authorization records, it was not possible to ascertain the extent to which the therapy terminations and delays were due to each of the reasons outlined in paragraph 1 above.

#### Methods

#### **Exception Events**

The participants with potential access problems arising from the Preferred Drug List were those who were denied a nonpreferred medication at the pharmacy at the time they submitted their prescriptions. The ACS data warehouse included denied pharmacy claims for the Indiana Medicaid program only for claims processed after ACS became the pharmacy claims processor for the State in late March 2003. Claims history data for earlier transaction dates, which were provided to ACS by the previous claims processor for the State, included only paid claims.



This limit on the availability of denied claims restricted the period for this type of study to denials in April 2003 or later. Only three groups of therapeutic classes had PDL implementations after that time; those starting in May, July and August of 2003. Because this study was part of a report on the PDL program through September 2003, the classes starting in August had too brief of an effective period to be reasonably studied. In addition to looking at the classes with recently implemented preferred drug lists, ACS also selected a sample of classes with earlier start dates to examine the potential effect of program maturity on issues of recipient access. The anti-hypertensive classes, which had start dates between September 2002 and January 2003, were selected for this analysis because of their relatedness to each other. This study covered the effect of nonpreferred drug list denials for the selected classes between May and September 2003.

ACS' claims processing system enabled the identification of denied claims for nonpreferred medications in the preferred drug list. Since a participant could be linked to multiple denials in a month for the same or related medications in the same therapeutic class, those multiple attempts in a month were grouped into a single exception event with a first deny date and last deny date. The next paid claim for a medication in the therapeutic class (or a related class if any)<sup>7</sup> on or after the first deny date was identified. Likewise, the most recent paid claim prior to the first denial date was identified. From our experience, multiple denials are often associated with a denied "nonpreferred" medication for which the pharmacist went ahead and filled the prescription without payment as to cause no delay in therapy, then attempted to resubmit the claim on occasion until the claim was paid. There is no systematic way to identify when this event occurs.

Participants were assigned to the various access outcomes described (i.e. denied claim with PA, denied claim without PA, follow-up prescription, no follow-up prescription) based on the number of days to a filled prescription or since a filled prescription. Participants with no follow-up fill and no other paid pharmacy claim in the months following the exception event were presumed to be ineligible and were thus assigned to that group. This approach was taken because participant eligibility information was maintained in the data warehouse only for those currently eligible.

#### **Prior Authorization**

Prior authorizations were specific to a medication at the National Drug Code (NDC) level. It was therefore possible to match PAs to specific therapeutic classes with preferred drug lists. ACS' claims processing system also included claim exception codes that indicated whether a PA was for a particular nonpreferred drug related to a preferred drug list or for other restrictions such as early refills, exceeding plan limitations, or Drug

<sup>&</sup>lt;sup>7</sup> All of the therapeutic classes used for hypertension therapy were considered as related in this analysis. All therapeutic classes starting with C4 were considered related to the C4LK class, with a preferred drug list implemented in May 2003. This included the C4N class that became subject to a preferred drug list in December 2002. The Fibric Acids were a sub-class of the M4E class, which also includes Statins, is considered as a related set of medications for this analysis.



Utilization Review (DUR) exceptions. A claim for an individual with an exception event in a therapeutic class was identified as being associated with a PA if there was a PA record for that person with an NDC code in the same therapeutic class and with the appropriate program codes.

#### **Results and Discussion**

Table 2.1 presents proportions of studied participants who experienced different outcome events as evidenced by prescription claims and prior authorization data. Table 2.2 provides results as the proportions of *exceptions* associated with each outcome. Potential recipients were the number of unique recipients of medications in a therapeutic class, plus the number of exception events that were not followed by the recipient receiving the same or a related medication within 30 days of the Event.

#### Access outcomes included:

- Exception events with follow up fill in same or related class on same day.
- Exception events with follow up fill in same or related class within 30 days.
- Exception events with no follow up fill within 30 days, but with a prior fill within 30 days of Event in same class.
- Exception events with no prior fill within 30 days and a follow up fill in same or related class more than 30 days after the event, or no follow up.
- Exception events with no follow up fill for which recipient was presumed to be ineligible because recipient had no other pharmacy claim of any kind in any month following exception event month (through January 2004).

General findings are presented below. There is also a section discussing the clinical aspects of the six individual classes with the highest rates of potential adverse access outcomes.

#### Conclusion 1: The proportion of users with an exception event was low.

Overall, 4462 (2.3%) of the average monthly users experienced a denied pharmacy claim. Individually, 1.5 % of the anti-hypertensive medication users, 3.1% of users of classes implemented in May, and 6% of users of classes implemented in July had an exception event (denied claim) in the period studied (Table 3.1). The higher rate associated with the classes implemented in July was to be expected, given the high proportion of recipients in that group who were on nonpreferred medications (Table 3.1).



#### Conclusion 2: Most exception events did not generate a prior authorization request.

The proportion of exception events associated with PAs ranged from 13% for the therapeutic classes implemented in May to 23.5% for the hypertensive group of therapeutic classes (Table 2.2). Given the low number of participants with no follow-up claim, the majority of the remaining exception events resulted in a change to a preferred medication. The July classes had an overall rate for exception events with PAs of 16%; however, individually, the classes in this group exhibited considerable variation, which ranged between 4% for the Otic Antibiotics to 75% for the Bone Formation Stimulating Drugs-Parathyroid Hormone Stimulating Type (a class containing only one medication, which was designated as nonpreferred).

In many PDL-related claim denial follow-up calls to ACS by prescribers or prescribers' representative from the prescriber's office, discussions took place with the ACS clinical pharmacist, but no requests were made for a PA and there were no PAs created in response to the calls. This might have been because the physician, after consultation about a patient's medical history, chose to change the medication (to a preferred alternative) or to discontinue the therapy. These discussion calls were not reflected in counts of the number PAs. The system that tracked those calls was not sufficiently complete to enhance this analysis with actual statistics for calls that resulted in therapeutic interchange or discontinuation as opposed to prior authorization.

#### Conclusion 3: Denied prior authorization requests did not affect access to medications.

Few therapeutic classes studied had any denied PA requests. In only two classes did more than 1 percent of the requests result in a denial (Table 2.2). The H3A class of brand name narcotics had a denial rate of 2.6% (10 denials), and the P4B class of bone formation stimulating drugs had a denial rate of 1.4% (1 denial). Most classes had no PA request that was denied. The pattern of very low denial rates existed from the beginning of the Preferred Drug List initiative in August 2002. Between August and December 2002, there were 17,775 PAs requested, of which 91 (only about 0.5%) were denied (see Table 2.3).

## Conclusion 4: Prior authorization requests did not cause additional delays in receipt of medication.

Exception events with PAs had a greater likelihood of being filled on the day of denial or within 30 days of the event (Table 2.1). With respect to the average number of days to a fill following an exception event, the results were mixed. For the anti-hypertensive classes, an exception event with a PA meant an average wait (if there was any delay at all) of 7.7 days, while events without PAs waited 8.6 days on average. For the PDL classes implemented in July, the wait for exception events with PAs was 7.2 days, compared to 6.6 days for those without.



## Conclusion 5: Delays in the receipt of medications were in part due to recipients seeking to refill their prescriptions too early.

There were recipients with no subsequent fills within 30 days after the exception event who had a fill within 30 days *prior* to the Event (Table 2.2). This outcome ranged from 2 percent of exceptions for the anti-hypertensive classes to 11 percent for the classes implemented in May. It was not possible to determine the extent to which early refills were the actual reason for a delayed fill, nor could it be determined, based on available data, the extent to which the delays might have been due to failures on the part of a pharmacist or physician to go through the prior authorization request process, or failures on the part of recipients to return to the pharmacy for an approved subsequent fill.

## Conclusion 6: Recipient ineligibility might explain why some exception events did not result in a prescription being filled for a medication in the class or a related class.

There were recipients with exceptions events, and no follow up fill, who were likely to have been (or who soon became) ineligible for Medicaid benefits. Those recipients were presumed to be ineligible because they had no paid pharmacy claims in the months following the month of the exception event, up through January 2004. Exception events associated with potential ineligibility represented 8% of the total Events for the antihypertensive classes, 6% for the classes implemented in May, and 5 percent for the July classes (Table 2.2).

## Conclusion 7: Relatively few eligible recipients with an exception event had no claims for follow up medication in the same or a related class within 30 days of the event.

Potential recipients who had no follow up claim for a medication in the same or a related class represented 0.78% of the users studied (0.3% of the potential users of the antihypertensive classes, 1.4% of the May PDL classes and 1.6% of the July PDL classes). This was equivalent to about 1,485 exception events per month with no follow up claim out of the total 188,508.

Therapy termination was an expected and potentially desirable outcome for the preferred drug list program. The PDL intervention was helpful in flagging cases of inappropriate therapy or therapy that was due to be discontinued. Therefore, some share of those exception events that were without follow up would be appropriate. Again, it was not possible to assess the degree to which exception events with no follow up medication were desirable or were instead the result of recipients, physicians or pharmacists who failed to follow through with their respective responsibilities.

A discussion of therapeutic classes with a high percentage of eligible recipients who appeared not to have received their medication for several months following their exception event:



#### A4F - Angiotensin Receptor Blockers (ARBs):

- ARBs: -- The share of potential ARB recipients with exception events who had no follow up claims for anti-hypertensive medication was 2.8%, compared to the anti-hypertensive group's overall average of 0.3%. This class also had a much higher proportion of recipients having exception events (14.3% compared to 1.5%) and a higher share of nonpreferred drug recipients (10.9% compared to 3.2%). However, recipients of drugs in this class who had exception events were more likely to have received a prior authorization and did not, on average, have any poorer outcomes than recipients of drugs in other anti-hypertensive classes (comparing values of the class with the "Total" values for the group in Table 2.1). In fact, the share of ARB exception events without any follow up, was 4.7%, which was much lower than the overall group average of 8.3%. Consequently, it did not appear that the high rate of potential ARB recipients with no follow up (2.8%) had much to do with the post-exception process. Rather a higher proportion of ARB recipients who were prescribed nonpreferred medications were affected by an exception in the first place.
  - ARBs Combined With Diuretics (ARBs w/Diuretics): -- The share of recipients in this combo class who received nonpreferred drugs was about half the rate of that for the users of ARBs alone (5.0% compared to 10.9%). The share of recipients with no follow up was proportional (1.4% compared to 2.8%), and the share of recipients with exception events was just over half (8.1% compared to 14.3%). On the other hand, half of the exceptions in this class were associated with PAs (14.6% compared to 28.9%); while those with an exception event were twice as likely to have no follow up fill (8.7% compared to 4.7%).
  - It was possible that most of these individuals with an exception and no follow up were "new" recipients since they also had not had a prior fill within 30 days of an anti-hypertensive medication. About 105 potential ARB (both with and without diuretics) recipients per month would appear to have been inappropriately prescribed an anti-hypertensive medication, or had providers who did not pursue the process for helping them secure the medication. Those individuals continued to see pharmacies and physicians after the exception, as they did have other (unrelated) prescriptions filled subsequently.

D7L - Bile Acid Sequestrants: -- This class appeared to be a significant outlier with 16.1% of the potential recipients having had no follow up claim. This statistic appeared driven in part by the high likelihood of a nonpreferred medication being prescribed (32.1% of recipients were on nonpreferred medications), which also increased the likelihood of a recipient having an event (25.9% of recipients had such an event). What appeared most significant was the very high proportion of exception events and potential recipients in this class that resulted in no follow up D7L medication (60.8% of events and 16.1% of potential recipients). However, of those potential recipients with no follow up claims, 16% were associated with an approved PA that appeared not to have been used. If Statins and Fibric Acid medications (the M4E class) were considered as related drugs, then the results changed substantially. Those D7L exception events with no follow up



claim decreased to 9.5% of potential recipients. Since this class of medications was often added onto other cholesterol medications, the clinical impact of this discontinuation was limited. Of note however, was that some dosage forms of the medications in this class were undesirable by participants and would likely be discontinued by some users if switched to one of these products.

<u>H6H – Skeletal Muscle Relaxants</u>: – Thirteen percent of the recipients of this class generated exceptions. Exceptions without any follow up medications composed 46% of the total exceptions and 6.4% of the potential recipients. The medications in this class were not intended for long-term use and many were addictive. For these reasons, therapy terminations in this class were likely to have been positive outcomes rather than negative.

P4B - Bone Formation Stimulating Drugs: -- This was an unusual class, having very few recipients (34) and having only one drug which was defined as nonpreferred. All P4B prescriptions without a PA incurred an exception event, which explains why this class had the highest proportion out of all classes of recipients with exceptions (62%) and why 75% of the exceptions were associated with a PA. (Note that recipients with existing PAs on record did not generate exceptions.) The exceptions resulting in no follow up medication represented 29.7% of the exceptions and 18.4% of the potential recipients. However, 37% of those individuals were associated with an approved PA, so it appeared that the follow up medication was simply never requested by the recipient in order to generate a claim.

Q6I – Eye Antibiotic/Corticosteroid Combos: -- Of all the classes studied for the access analysis, this class had the highest rate of exception events without follow up: 20.4% of the recipients had no follow up claim. This class had the second highest rate of recipients generating exceptions after the P4B class (60.7%), even though only about half of the Q6I recipients (52.8%) had nonpreferred medications. The medications included in this class were used for acute infections where the initial supply was often the only supply needed. Further, most medications in this class were relatively inexpensive. Possible scenarios that might have been occurring, but which were impossible to ascertain from prescription claims data, included the physician dispensing samples instead of sending the participant back to the pharmacy, cash purchase by the recipient, or the pharmacist providing medication in anticipation of approval. Therefore, a relatively low proportion of exception events were associated with PAs (14.5%).

#### Conclusion

In this analysis, 2.3% of recipients of drug classes subject to the PDL experienced an exception event (range of 1.5% of recipients of antihypertensives to 6% of the recipients of drugs classes with PDL implementations in July 2003). Overall, only 0.78% of recipients studied did not have a claim for the same medication or one in a related class within 30 days of the exception. Over half of these follow-up claims were processed on the same day that the exception event was generated. The percent of eligible participants experiencing an exception event, and not receiving a medication within 30 days of the



event, ranged from 0.3% for the antihypertensive classes to 1.6% for the PDL classes implemented in July 2003.

Not all delays or therapy terminations associated with a preferred drug list program should be considered detrimental. Claims data does not allow explanation for the therapy interruptions. Since pharmacy claims data were the only source of information available to perform this analysis, it is impossible to determine which delay/terminations were clinically appropriate. For example, there are many potential reasons for the observed delays or terminations, other than PDL, such as: physician sampling of medications, other third party liability, patient compliance, or changes in patient therapy. Some of the reasons why delays/terminations occur are positive with respect to improved care and reduced risk. Understanding the full explanation for therapy interruptions would require additional investigation (e.g. recipient, pharmacy, and physician surveys).



#### **Table 2.1**

Table 2.1. Outcomes as a Percent of Total Users In Class and Overall

		orizations	comes as a reicen	. c. rotal occió		Unique U	sers
Therapeutic Class	% of Users Associated With PAs	% of Users Denied a PA	% of Established Users With Exceptions Not Filled Within 30 Days	% of All Users With Exceptions and No Fill Within 30 Days	% of Users W/ Exceptions Presumed Ineligible	% of Potential Users Who Had Exceptions	Average Users Per Month
ANTI HYPERTENSIVE DRUG CLASSES IMPLEMENTED ON VARIOU	S DATES						
A4D - ACE Inhibitor	0.29%	0.00%	0.03%	0.32%	0.17%	1.9%	20,312
A4D - ACE Inhibitor W/Diuretics	0.06%	0.00%	0.03%	0.07%	0.13%	0.4%	1,735
A4F - Angiotensin Receptor Blockers	4.33%	0.00%	0.31%	2.76%	0.71%	14.3%	2,557
A4F - Angiotensin Receptor Blockers w/Diuretics	1.29%	0.01%	0.17%	1.41%	0.77%	8.1%	2,074
A4K - Ace Inhibitor w/CCB	0.30%	0.00%	0.04%	0.32%	0.07%	1.8%	1,377
A9A - Calcium Channel Blockers	0.12%	0.00%	0.01%	0.08%	0.05%	0.3%	17,208
J5D - Beta Agonists	0.95%	0.00%	0.09%	0.60%	0.32%	3.0%	17,627
J7A/B/C - ALPHA/BETA Adrenergic Blockers	0.00%	0.00%	0.00%	0.00%	0.00%	0.0%	21,411
R1M - Loop Diuretics	0.00%	0.00%	0.00%	0.00%	0.00%	0.0%	20,247
Total for Group	0.37%	0.00%	0.03%	0.28%	0.13%	1.5%	104,549
PREFERRED DRUG LIST CLASSES IMPLEMENTED IN MAY 2003							
C4K - Antidiabetic Agents	0.04%	0.00%	0.03%	0.09%	0.02%	0.2%	9,468
C4N - Thiazolidenediones (Implemented in December)	0.09%	0.00%	0.02%	0.09%	0.09%	0.5%	5,608
D7L - Bile Acid Sequestrants	5.83%	0.05%	2.89%	16.11%	0.57%	25.9%	422
H3A - Brand Name Narcotics	0.19%	0.00%	0.11%	0.26%	0.07%	1.2%	41,273
H6H - Skeletal Muscle Relaxants	1.49%	0.01%	1.90%	6.40%	0.87%	13.0%	10,986
R1A - Urinary Tract Antispasmodic/Anti Incontinence Agents	0.62%	0.00%	0.09%	2.21%	0.10%	3.3%	6,489
Total for Group	0.42%	0.00%	0.37%	1.39%	0.19%	3.1%	74,246
PREFERRED DRUG LIST CLASSES IMPLEMENTED IN JULY						0.0%	0.0%
J3A - Smoking Cessation	0.06%	0.00%	0.06%	0.30%	0.00%	1.1%	558
N1C - Leukocyte Stimulants	7.75%	0.00%	1.41%	5.63%	0.00%	26.1%	47
P4B - Bone Formation Stimulating Agents	46.60%	0.97%	6.80%	18.45%	0.00%	62.1%	34
Q6G - Miotics/Other intraocular Pressure Reducers	0.84%	0.00%	0.22%	0.69%	0.05%	4.4%	3,472
Q6I - Eye Antibiotic/Corticosteroid Combos	9.47%	0.00%	3.71%	20.36%	4.66%	60.7%	422
Q6U - Ophthalmic Mast Cell Stabilizers	1.48%	0.00%	0.49%	6.73%	0.99%	22.0%	203
Q6W - Ophthalmic Antibiotics	0.33%	0.00%	0.17%	0.85%	0.29%	3.4%	2,612
Q8F/W - Otic Antibiotics	0.01%	0.00%	0.00%	0.04%	0.00%	0.4%	2,364
Total for Group	1.04%	0.00%	0.33%	1.62%	0.32%	6.1%	9,713
Overall Count (Percentage)	807 (0.43%)	4 (0.0%)	346 (0.18%)	1,485 (0.79%)	309 (0.16%)	4,419 (2.3%)	188,508



**Table 2.2** 

	Prior Author	izations		Ex	ception Cas	AS			Hadana I	llaara		
								Unique Users				
					% of	% of			Potential			
					Exceptions	Exceptions	% of		Users Who			
					Not Filled	With Fill	Exceptions		Had			
Preferred Drug List Therapeutic Class					Within 30	After 30	With No	% of	Exceptions	Average		
	% of		% of	% of	Days But	Days or No	Follow Up	Potential	and No	Number of	Non-	
1	Exceptions	% of	Exceptions	Exceptions	With Prior	Fill and No	Fill -	Users Who	Claim	Potential	Preferred	
	Associated	PAs	Filled on	Filled Within	Fill Within	Prior Fill In	Presumed	Had	Within 30	Users Per	User	
	With PAs	Denied	Same Day	30 Days	30 Days	30 Days	Ineligible	Exceptions	Days	Month	Share	
	(1)	(2)	(3)	(4)	<u>(5)</u>	(6)	<u>(7)</u>	(8)	(9)	(10)	(11)	
ANTI HYPERTENSIVE DRUG CLASSES IMPLEMENTE	D ON VARIO	OUS DAT	ES									
A4D - ACE Inhibitor	14.0%	0.0%	34.1%	40.8%	1.5%	15.5%	8.2%	1.9%	0.3%	20,312	1.6%	
A4D - ACE Inhibitor W/Diuretics	10.0%	0.0%	30.0%	30.0%	6.0%	12.0%	22.0%	0.4%	0.1%	1,735	9.9%	
A4F - Angiotensin Receptor Blockers	28.9%	0.0%	36.4%	38.3%	2.1%	18.4%	4.7%	14.3%	2.8%	2,557	10.9%	
A4F - Angiotensin Receptor Blockers w/Diuretics	14.6%	0.7%	35.7%	37.7%	2.0%	15.9%	8.7%	8.1%	1.4%	2,074	5.0%	
A4K - Ace Inhibitor w/CCB	16.2%	0.0%	30.0%	46.9%	2.3%	16.9%	3.8%	1.8%	0.3%	1,377	1.3%	
A9A - Calcium Channel Blockers	34.8%	0.0%	37.7%	22.8%	1.7%	23.8%	13.9%	0.3%	0.1%	17,208	1.8%	
J5D - Beta Agonists	29.0%	0.0%	37.8%	31.4%	2.7%	18.2%	9.9%	3.0%	0.6%	17,627	4.1%	
J7A/B/C - ALPHA/BETA Adrenergic Blockers	31.3%	0.0%	18.8%	50.0%	0.0%	25.0%	6.3%	0.014%	0.004%	21,411	6.1%	
R1M - Loop Diuretics	22.2%	0.0%	33.3%	44.4%	0.0%	22.2%	0.0%	0.009%	0.002%	20,247	0.6%	
Overall	23.5%	0.1%	36.1%	36.0%	2.1%	17.5%	8.3%	1.5%	0.3%	104,549	3.2%	
Those With a PA			38.6%	47.3%	2.0%	11.2%	0.9%					
PREFERRED DRUG LIST CLASSES IMPLEMENTED IN	N MAY 2003											
C4K - Antidiabetic Agents	20.9%	0.0%	15.1%	8.1%	16.3%	50.0%	10.5%	0.2%	0.1%	9,468	0.2%	
C4N - Thiazolidenediones (Implemented in December)	15.2%	0.0%	42.1%	23.4%	4.1%	15.2%	15.2%	0.5%	0.1%	5,608	4.9%	
D7L - Bile Acid Sequestrants	22.0%	0.8%	11.8%	14.3%	10.9%	60.8%	2.1%	25.9%	16.1%	422	32.1%	
H3A - Brand Name Narcotics	14.7%	2.6%	32.1%	33.0%	9.0%	20.5%	5.4%	1.2%	0.3%	41,273	3.0%	
H6H - Skeletal Muscle Relaxants	10.7%	0.9%	16.7%	17.4%	13.7%	46.0%	6.3%	13.0%	6.4%	10,986	7.9%	
R1A - Urinary Tract Antispasmodic/Anti Incontinence A	18.1%	0.0%	11.5%	18.7%	2.6%	64.3%	2.9%	3.3%	2.2%	6,489	3.1%	
Overall	12.9%	1.1%	19.6%	20.8%	11.4%	42.5%	5.7%	3.1%	1.4%	74,246	3.6%	
Those With PA	0.0%	0.0%	21.5%	29.1%	14.3%	33.8%	1.2%					
PREFERRED DRUG LIST CLASSES IMPLEMENTED IN	N JULY											
J3A - Smoking Cessation	5.6%	0.0%	44.4%	22.2%	5.6%	27.8%	0.0%	1.1%	0.3%	558	18.0%	
N1C - Leukocyte Stimulants	29.7%	0.0%	43.2%	29.7%	5.4%	21.6%	0.0%	26.1%	5.6%	47	6.0%	
P4B - Bone Formation Stimulating Agents	75.0%	2.1%	25.0%	34.4%	10.9%	29.7%	0.0%	62.1%	18.4%	34	100.0%	
Q6G - Miotics/Other intraocular Pressure Reducers	18.8%	0.0%	46.8%	31.7%	5.0%	15.5%	1.1%	4.4%	0.7%	3,472	26.4%	
Q6I - Eye Antibiotic/Corticosteroid Combos	14.5%	0.0%	37.8%	18.2%	5.7%	31.2%	7.1%	60.7%	20.4%	422	52.8%	
Q6U - Ophthalmic Mast Cell Stabilizers	6.4%	0.0%	35.0%	29.3%	2.1%	29.3%	4.3%	22.0%	6.7%	203	50.2%	
Q6W - Ophthalmic Antibiotics	8.9%	0.0%	45.4%	19.2%	4.5%	23.0%	7.9%	3.4%	0.9%	2,612	15.8%	
Q8F/W - Otic Antibiotics	4.0%	0.0%	72.0%	16.0%	0.0%	12.0%	0.0%	0.4%	0.0%	2,364	2.0%	
Overall	16.2%	0.3%	41.2%	23.4%	5.1%	25.3%	5.0%	6.1%	1.6%	9,713	18.5%	
Those With a PA			49.8%	33.3%	3.6%	12.2%	1.0%					



# CHAPTER 3. Pharmacy Prior Authorizations Associated with the Preferred Drug List Program

Between August 2002 when the PDL program began to December 31, 2002, there were 17,866 Preferred Drug List (PDL) program prior authorizations (PA's) requested, 17,775 were approved (99.5%) and 91 were denied (0.5%).

During calendar year, 2003 (1/1/03 to 12/31/03) there were 53,604 PDL program prior authorizations requested. Of the 53,604 PA's requested, 52,054 were approved (97.1%), 165 were denied (0.3%) and 1,385 were suspended<sup>8</sup> (2.6%).

Between January 1, 2004 and April 30, 2004, there were 18,470 PDL program prior authorizations (PA's) requested. Of the 18,470 PA's requested, 18,200 were approved (98.5%), 91 were denied (0.5%) and 179 were suspended (1.0%).

<sup>&</sup>lt;sup>8</sup> Suspended PA's are PA's that require additional information before the PA is denied or approved.



#### **TABLE 3.1**

# NUMBER OF PRIOR AUTHORIZATIONS ISSUED BETWEEN AUGUST 2002 AND DECEMBER 2002 BY THERAPEUTIC CLASSES WITH PREFERRED DRUG LISTS IN EFFECT AT THE TIME WITH COUNT OF DENIALS

	Count of PAs	Count of	
	Between August and December	Count of Denied	
PDL Therapeutic Class	2002	PAs	% Denied
1 DE Morapeano Olaso	<u>2002</u> 1	1710	0.0%
A4D - ACE Inhibitor	594		0.0%
A4D - ACE Inhibitor W/Diuretics	2		0.0%
A4F - Angiotensin Receptor Blockers	1		0.0%
A4F - Angiotensin Receptor Blockers w/Diuretics	5		0.0%
A4K - ACE Inhibitor w/CCB	16		0.0%
A9A - Calcium Channel Blockers	71		0.0%
C4N - Thiazolidenediones	16		0.0%
D4K - Proton Pump Inhibitors	13,289	90	0.7%
H3F - Triptans	29		0.0%
J5D - Beta Agonists	258	1	0.4%
J7A/B/C - ALPHA/BETA Adrenergic Blockers	1,790		0.0%
M4E - Statins	9		0.0%
M9P - Platelet Aggregation Inhibitors	84		0.0%
P5A - Inhaled Glucocorticoids	97		0.0%
R1M - LOOP Diuretics	22		0.0%
Z2A - Non-Sedating Antihistamines	1,491		0.0%
TOTAL	17,775	91	0.5%



### Table 3.2 Calendar Year 2003 PA's Related to the PDL Program



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: 5/14/2004 Client ID: INCAID

From 01/01/2003 To 12/31/2003

Therapeutic Class or Preferred Drug Description	Α	D	S
ACE Inhibitors	594	1	
ACEI with CCB	191		
ACEI with Diuretics	30		
Angiotensin Receptor Blockers (ARBs)	3.824	5	2
Antidiabetic Agents	672	1	
Antiemetic - Antivertigo Agents	66		
Antifungal Oral	848	1	
Antifungal Topicals	602		
Antipsoriatics	3		
Antiulcer- H Pyloric Agents	168		
Antiviral Anti-herpetic Agents	148		
Antiviral Influenza Agents	429		
ARBs with Diuretics	243	2	1
Beta Adrenergic Blockers	211		
Bile Acid Sequestrants	146	2	
Brand Name Narcotics	466	1	
Brand NSAIDS	6.493	61	992
Calcium Channel Blockers	284		
Cephalosporins	482		
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	40		
Duragesic	2,315	4	18
Fibric Acids	84	·	
Fluoroquinolones	402		
Forteo	59	2	
H2 Antagonists	2,464	11	183
Heparin and Related Products	4		
HMG CoA Reductase Inhibitors	631	2	
Imitrex Tablets Month Limit	51		
Inhaled Glucocorticoids	1.026		
Leukocyte Stimulants	18		
Leukotriene Receptor Antagonists	24		
Long Acting Beta Agonists	239	1	
Loop Diuretics	21		
Macrolides	276		1
Miotics - OIPR	94		
Non-Sedating Antihistamines	1,789	4	
Ophthalmic Antibiotics	368		
Opthalmic Mast Cell Stabilizers	89	1	
Oral Antifungals	49	1	
Otic Antibiotics	55		
Oxycodone and Hydrocodone APAP	145	23	12
Oxycodone IR	109	1	4
Oxycontin	797	2	16
Platelet Aggregation Inhibitors	143		
PROPOXYPHENE WITH APAP	24		
Proton Pump Inhibitors	15,632	12	13

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### Table 3.1 – continued --



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date: 5/14/2004

From 01/01/2003 To 12/31/2003

Short Acting Beta Agonists	3,049	3	1
Skeletal Muscle Relaxants	945	1	
Smoking Deterrent Agents	73		
Systemic Vitamin A Derivatives	164		
Thiazolidenediones	1,207		3
Triptans	449		
Ultram and Ultracet	1,242	18	137
Urinary Tract Antispasmodics- Antiincontinence	271		
Vaginal Antimicrobials	736	2	
Zithromax Limit - PDLZPAK	112		
Zofran Tablet Limit (10 tablets per Rx)	15		
Sum:	52,054	165	1,385



### Table 3.2 January 1, 2004 to April 30, 2004 PA's Related to PDL Program



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Key: A=Approved D=Denied S=Suspended

Run Date: 5/14/2004 Client ID: INCAID

#### From 01/01/2004 To 04/30/2004

Therapeutic Class or Preferred Drug Description  ACE Inhibitors		l D	S
ACE INDIDITORS	435		
ACEI with CCB	44	1	
ACEI with Diuretics	28	1	
Angiotensin Receptor Blockers (ARBs)	986	3	
Antidiabetic Agents	100		
Antiemetic - Antivertigo Agents	21		
Antifungal Oral	279	1	1
Antifungal Oral Antifungal Topicals	205		'
Antipsoriatics	2		
Antiulcer- H Pyloric Agents	131	1	1
Antiviral Anti-herpetic Agents	135		<u> </u>
Antiviral Influenza Agents	101	1	
ARBs with Diuretics	75	<u> </u>	
Beta Adrenergic Blockers	68		
Beta Adrenergics & Corticosteroids	366	1	
Bile Acid Sequestrants	47		
Brand Name Narcotics	437	2	
Brand NSAIDS	801	35	159
Calcium Channel Blockers	139	3	.55
Cephalosporins	223	3	
Diflucan 150mg 2 Tablet Limit PDLDIFLUCAN	2		
Duragesic	308		
Fibric Acids	482		
Fluoroquinolones	126	1	
Forteo	29	4	
H2 Antagonists	3	'	
Heparin and Related Products	8		
HMG CoA Reductase Inhibitors	232	1	2
Imitrex Tablets Month Limit	4		
Inhaled Glucocorticoids	481	1	
Leukocyte Stimulants	9		
Leukotriene Receptor Antagonists	1,221		4
Long Acting Beta Agonists	99		
Loop Diuretics	43	1	
Macrolides	56		
Miotics - OIPR	78		
Non-Sedating Antihistamines	819	2	
Ophthalmic Antibiotics	253	1	
Opthalmic Mast Cell Stabilizers	45		
Oral Antifungals	18		
Otic Antibiotics	40	1	
Oxycodone and Hydrocodone APAP	10		
Oxycodone IR	2		
Oxycontin	119		1
Platelet Aggregation Inhibitors	60		
PROPOXYPHENE WITH APAP	1	1	
Proton Pump Inhibitors	5,682	18	9

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5/14/2004

#### -- continued --**Table 3.2**



#### Indiana Medicaid - Preferred Drug List Prior Authorizations

Run Date:

#### From 01/01/2004 To 04/30/2004

SERMS - Bone Resorption Agents	236		
Short Acting Beta Agonists	1,062	2	
Skeletal Muscle Relaxants	471	3	
Smoking Deterrent Agents	18		
Systemic Vitamin A Derivatives	23		
Thiazolidenediones	716		2
Triptans	153	1	
Ultram and Ultracet	3		
Urinary Tract Antispasmodics- Antiincontinence	121		
Vaginal Antimicrobials	530	2	
Zithromax Limit - PDLZPAK	12		
Zofran Tablet Limit (10 tablets per Rx)	2		
Sum:	18,200	91	179



# CHAPTER 4. Pharmacy Benefit Expenditure Changes Associated with the Preferred Drug List Program

This Chapter explores the economic impact of the Preferred Drug List (PDL) program on the pharmacy benefit component of the Indiana State Medicaid Program. The analysis is based on claims paid August 2002 through September 2003.

The "Methods" section describes how pharmacy reimbursement data is integrated with CMS rebate data to estimate the net cost savings for individual PDL classes, taking into account background variability such as price changes, rebate amount changes and seasonal variation in medication use.

The section on "Factors Affecting PDL Program Savings" highlights the effect of CMS federal rebates, preferred drug selection, shifting market share, and utilization on the net cost savings. The dynamic nature of these factors may impact the various therapeutic classes on the Preferred Drug List in different ways. Therefore, in the section on "Performance of Individual Therapeutic Classes Subject to Preferred Drug List," the performance outcomes and some of the factors that affect the outcomes are summarized.

The "Results" section of this chapter reports the overall preferred drug market share changes, estimated expenditure changes, estimated rebate receipt changes, and estimated net savings experienced by the State. It is important to understand that one consequence of shifting utilization to lower priced medications is a potential reduction in CMS rebates. The CMS rebate reduction can be greater than the expenditure savings for a given therapeutic class.

#### Introduction

The Indiana Medicaid Preferred Drug List (PDL) program was instituted to improve the quality of pharmacy care and to reduce pharmacy benefit expenditures. The PDL program involves the review and selection of therapeutic alternatives within specific therapeutic classes by the Indiana Medicaid Therapeutics Committee (T Committee). The Indiana Medicaid Drug Utilization Review (DUR) Board then considers these recommendations. Through this process, drugs are designated as "preferred" or "nonpreferred" based on their ability to produce positive clinical outcomes and savings to the State. Since clinical considerations are the primary basis for preferred drug selection, scenarios existed where there are no cost savings associated with choosing a particular drug within a therapeutic class. Drug costs are defined as the price paid to the pharmacy less rebates paid to the State by drug manufacturers. The rebates presently received by Indiana Medicaid are those mandated by the federal government through Centers for Medicare and Medicaid Services (CMS) regulations. Changes in rebate amounts arising from market share shifts to other medications within a class affected net savings to the State.



The PDL program shifts utilization from nonpreferred to preferred medications based upon clinical efficacy. If clinical efficacies of the drugs are equivalent, then the less expensive drugs are encouraged. Prescribers of nonpreferred medications are encouraged to consider prescribing less expensive drugs with equivalent clinical efficacy that are listed as the preferred drugs. Point-of-service edits are used to identify prescriptions for nonpreferred medications during the adjudication process. The dispensing pharmacist may then contact the prescribing physician to request a prescription for a preferred medication. Alternatively, the prescribing physician may consult with an ACS pharmacist regarding the medical need for the nonpreferred medication. These discussions are based upon the patients' known medical history, previous unsuccessful trials of preferred drugs, or other mitigating circumstances. Possible outcomes included approval for patients to remain on the nonpreferred medication, changing to a preferred medication, or discontinuation of therapy. The approval for nonpreferred medications is processed through the prior authorization (PA) process, allowing the dispensing of a specific nonpreferred medication for up to 12 months. Clinical concerns have priority within the prior authorization process. Therefore, a recipient with a substantiated need for a nonpreferred medication will be allowed that medication as long as the prescribing physician is willing to request prior authorization. In some cases, through these discussions between an ACS pharmacist and the prescriber, it is determined that the prescribed medication is duplicative or unnecessary. In these cases, the PDL may achieve even greater health benefits for recipients.

#### **Methods**

#### Extraction of CMS Rebate Data

Rebate data is available in the ACS Data Warehouse. The CMS data provides a unit rebate amount (URA) for each national drug code (NDC)<sup>9</sup>, the applicable quarter of service, a termination date if needed, and a load date indicating when the record was loaded into the warehouse. Data loads occur quarterly and often include new records updating the URA for earlier quarters of service. Working with an extract of CMS rebate data that extended from the first quarter of 2001 through the third quarter of 2003, ACS found that there were multiple records (up to 18) for about 48 percent of the NDC/quarter of service combinations. There might have been a sequence of several quarters with zero values. About 19 percent of the NDC/quarter of service combinations initially had a zero value; about 8 percent of all the combinations in the extract still had a zero value after the multiple loads covered by this extract. The URA values in multiple-record situations generally did not change if there was a value greater than zero; but about 9.5 percent did change (51 percent of these changes resulted in increases and 49 percent resulted in reductions between the first and last values that were greater than zero). The magnitudes of the changes ranged significantly. The large changes (some were over 1000 percent) indicated data entry errors.

<sup>&</sup>lt;sup>9</sup> NDC refers to the National Drug Code number that uniquely identifies all commercially marketed drug products by their name, strength, package size, delivery route and manufacturer/distributor.



In light of the above problems, in order to provide a reasonable basis for estimating the ultimate rebate effect of a PDL, the unit rebate amounts were "fixed" when necessary. The basic file consisted of the latest URA available for each quarter of service that was greater than zero. If there were no values greater than zero for an NDC/quarter of service combination<sup>10</sup>, then a value greater than zero for that NDC was borrowed from the nearest adjacent quarter, searching forward and backward. If that method failed to populate the URA cell, then the minimum URA that was greater than zero for that NDC's drug name and quarter of service across all NDC's was used, if one existed. If the value was still zero, then no further effort was made to fix the missing URA value for that NDC/quarter of service combination.

A comparison was then made between the URA and the average allowed unit ingredient amount for the NDC in a month of service to identify outliers for correction. If the URA was greater than 80 percent of the unit ingredient amount further adjustments were made to reduce it. A search was made in adjacent quarters to find a valid URA for that NDC that was lower than the one flagged. The remaining URAs for an NDC/month of service combination with a value greater than 80 percent of the allowed unit ingredient amount were reduced to that value. Next, the URA was reduced to zero if, in a month, the total rebate amount (URA times quantity) was greater than the total amount paid for the NDC in a month. Those situations appeared to be caused by submission of charges that were lower than the sum of the allowed ingredient amount plus dispensing fee, or by the existence of TPL (third party liability), offsets that reduced the amount paid. Finally, URAs were also reduced to zero if the last day of the month of service was greater than the CMS termination date, when such a date existed in the database for the NDC.

The total rebate amount was divided by the number of claims for the NDC in a month to calculate the rebate per claim, and that amount was subtracted from the expenditure per claim to calculate the net expenditure per claim.

A crosswalk table enabled assignment of individual NDC rebate amounts to each drug in all the classes by month of service.

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<sup>&</sup>lt;sup>10</sup> Just over 5 percent of the NDC/month-of-service combinations required for the Indiana study were missing URA values. The missing URAs involved about 4 percent of the claims. The above described search process found appropriate URA values for 90 percent of the claims with missing URAs.

<sup>&</sup>lt;sup>11</sup> Two percent of NDC/month-of-service combinations (and less than 1 percent of the claims used in this study) had ratios of URA to allowed unit ingredient amount of more than 0.80. About 2/3 of the outlier claims were fixable by searches for reasonable values from adjacent quarters. A random review of the remaining NDC's with these outlier ratios indicated that most followed a consistent pattern and did not evidence changes indicative of data entry errors. Many high ratios were related to allowed ingredient amounts that were low relative to the amount paid. In those cases, a reduction in the URA to 0.80 of the allowed unit ingredient amount resulted in an underestimation of the rebate amount. In those cases where the URA was erroneous and *not* fixed through the search process, this systematic adjustment may have resulted in an overestimation of the rebate amount. Fortunately, most of the outlier cases involved NDC's with few claims per month.



#### Preferred Drug List Savings Calculations

The method used for estimating PDL savings was based on market share changes for all medications in a therapeutic class covered by the PDL. This included drugs identified as preferred and nonpreferred. The method estimated savings for each therapeutic class impacted by the PDL; beginning with the month the therapeutic class was added to the PDL. For each class, month of service, and NDC in the class, the amount paid per claim, the rebate per claim, the net expenditure per claim<sup>12</sup>, and the NDC's market share <sup>13</sup> of total claims were calculated for all the drugs in that class. Multiplying each NDC's market share times its average amount (e.g., paid per claim) and then adding those products for all NDC's in the class was how the overall average per claim amounts for each class were calculated. Those average amounts were the "observed" or "actual" average amount paid per claim, average rebate amount per claim and average net expense per claim (See columns 4, 5 and 6 in Example 1 below).

EXAMPLE 1. Payment Savings Per Claim Calculation for First Month of Operation with Preferred Drugs

	Prior	Month			First Mor	nth of Service	
	Market	Paid Pe	r Actual	Market	Paid per	Observed	Expected Weighted
	Share	Claim	Weighted	Share	Claim	Weighted	With Market Share Change
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
			(1)X(2)			(4)X(5)	(1)X(5)
Preferred Dru	igs in The	rapeutic C	lass				
Drug A	.15	\$30.00	4.50	.25	\$32.00	8.00	4.80
Drug B	.20	\$35.00	7.00	.32	\$35.00	11.20	7.00
Drug C	.15	\$25.00	3.75	.30	\$27.00	8.10	4.05
Nonpreferred	Drugs in	Therapeut	ic Class				
Drug D	.25	\$60.00	15.00	.05	\$62.00	3.10	15.50
Drug E	.20	\$55.00	11.00	.05	\$55.00	2.75	11.00
Drug F	.05	\$75.00	3.75	.03	\$70.00	2.10	3.50
Overall Aver	age Paid:						
As observ	ed for pric	or month				\$45.00	
	-	nth of serv	ice			\$35.25	
As expect	ed for mo	nth of serv	ice			\$45.85	
Monthly s	avings-pe	r-claim for	month of se	ervice		\$10.60	
Prior mon	th's total	savings-pe	r-claim			\$ 0.00	
			st month of	service		\$10.60	
			rational in p		h.)		

<sup>12</sup> Net expenditure per claim was the amount paid per claim less the rebate amount per claim.

<sup>&</sup>lt;sup>13</sup> An NDC's market share was the NDC's percentage share of all claims for the medications in the therapeutic class on the PDL in a given month. If, for example, in a month of service, there were 2,500 claims for an NDC and there were 12,000 claims for all the preferred and nonpreferred medications in the NDC's therapeutic class, then the NDC's market share for that month would be 20.6 percent.



For each class and month of service, the "expected" payment per claim, an "expected" rebate per claim, and an "expected" net expense per claim were calculated. The "expected" amounts corresponding to what the average values would have been in that month of service had the market share of medications in the class not changed<sup>14</sup>. The calculations were the same as for the "observed" amounts except that the prior month's market share for each NDC was used with the service month dollar value. (See columns 1, 5, and 7 in Example 1.)

The difference between the expected amount paid per claim and the observed paid per claim was the monthly payment savings-per-claim. The difference between the expected rebate per claim and the observed rebate per claim was the monthly rebate change per claim. The difference between the expected net expense per claim and the observed net expense per claim was the monthly net savings per claim. If there were no differences between the prior month's market share distribution and that of the service month (i.e., column 4 equals column 1), then there were no savings for that service month.

During the month following a PDL implementation, the monthly savings-per-claim values calculated for each month of service became additive. The "total" savings-per-claim for a month of service was the total savings-per-claim for the prior month plus the monthly saving-per-claim for that month. For the first month of operation, initial total savings-per-claim was typically large, reflecting significant shifts in market share. The savings achieved that month through market share change should continue forward to be increased/decreased by the effects of the subsequent month's market share changes (see Example 2). As market changes stabilized following implementation of the preferred drug list, the monthly savings-per-claim diminished but monthly savings-per-claim values continued to be additive. If there was reversion toward previous prescribing practices, the method captured the effects of such changes and reduced the total savings-per-claim. If there was a new medication in the class, the method picked up the effects of market shifts to the new drug from other medications in the class.

<sup>&</sup>lt;sup>14</sup> The baseline of change for estimating savings for each month of service was the prior month of service, including the first month of service in which a preferred drug list was being implemented. For example, for

therapeutic classes having a preferred drug list with implementation starting in September 2002, the first month of service for which savings were estimated was September 2002 and the baseline month (i.e., prior month) was August 2002.



EXAMPLE 2. Payment Savings Per Claim Calculation for Second Month of Operation

	Prior N	Month (First	Month)	Mon	th of Serv	vice (Seco	ond Month)
	Market	Paid P	er Actual	l Market	Paid per	Observ	ved Expected Weighted
		Share	Claim	Weighted	Share	Claim	Weighted With Market Share Change
	(1)	(2)	(3)	(4)	(5)	(6)	(7)
			(1)X(2)	1		(4)X	$X(5) \qquad (1)X(5)$
Preferred Dr	ugs						
Drug A	.25	\$32.00	8.00	.30	\$33.00	9.90	8.25
Drug B	.32	\$35.00		.32	\$33.00	10.56	10.56
Drug C	.30	\$27.00	8.10	.29	\$28.00	8.12	8.40
Nonpreferred	d Drugs						
Drug D	.05	\$62.00	3.10	.04	\$63.00	2.52	3.15
Drug E	.05	\$55.00	2.75	.03	\$54.00	1.62	2.70
Drug F	.03	\$70.00	2.10	.02	\$65.00	1.30	1.95
Overall Ave	rogo Doid						
Observed	_					\$35.25	
		Monui h of Service				\$33.23	
		of Service	Mandla a£	Camaiaa		\$35.01	
	_	Per Claim fo		Service		\$00.89	
		al Savings-p		:		\$10.60	
1 otai Sav	ings-per-	claim for M	onun of Ser	vice		\$11.49	

Total payment savings in a month were the product of the month's total payment savingsper-claim and the number of claims for all drugs in the class. Total rebate changes and net savings were similarly calculated using the number of claims in the month.

This savings-per-claim method was used to monitor the consequences of market share changes over time for any group of medications. The method required knowing the group of drugs to be included (which may be defined by therapeutic class, drug name, GCN, or NDC), but did not require knowing which were preferred or nonpreferred. <sup>15</sup> The method easily accommodated new drugs as they were added and the elimination of other products as they decreased in utilization. Changes in the preferred status of drugs in a class with a preferred drug list occurred with this method without having to alter or rebase the calculations for the new definitions. If there were shifts from one to another preferred medication, the method captured the effect of such changes.

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<sup>&</sup>lt;sup>15</sup> It is, of course, still important to know which drugs were preferred/nonpreferred each month in order to track the degree to which prescribing has been changed to preferred medications over time.



#### **Factors Affecting PDL Program Savings**

#### CMS Rebates

CMS rebates have a significant impact on the financial performance of a PDL program. Pharmaceutical manufacturers must participate in the CMS rebate program if they desire to be reimbursed by State Medicaid agencies. This program requires that a portion of the applicable drug expenditure be paid back (rebated) to the State by the manufacturer. For generic medications, the Medicaid rebate is 11 percent of the average manufacturer's price (AMP) for the quarter in which the prescription was filled. For branded medications, the *minimum* Medicaid rebate is 15.1 percent of AMP for the quarter of service. The brand medication rebate may exceed this percent for one of two reasons, the best price (BP) or the consumer price index adjustment (CPI)<sup>16</sup>. These calculations and adjustments are made each quarter to determine the Medicaid rebate owed to the State for drugs dispensed in each quarter of service. Variations in rebate amounts for a medication from one quarter to the next are often due to the purchasing practices of large payer groups. If a payer negotiates a low price for a certain medication purchases that medication in two quarters of the year, the Medicaid rebate could have a positive impact for those quarters.

The reported rebate amounts for a specific drug in a particular quarter of service may have some variability. This fluctuation is due to the accumulation of data that changes the AMP, BP or CPI adjustment values for that drug. Finally, there are missing and erroneous values (e.g., decimal in wrong place or bad data entry) to contend with while working with the CMS rebate data. The reported CMS unit rebate amount for a quarter of service is often zero for several reporting periods because CMS and the manufacturer might be disputing the amount. For example, missing and erroneous values that are corrected in the next quarter of CMS rebate data may cause the rebate amounts to be one amount now & another "corrected" amount 3 months from now.

These factors may cause the rebate amounts to vary each time they are calculated. The "Methods" section of this chapter discusses the extraction and use of CMS unit rebate data to estimate potential rebate receipts for all medications in each affected therapeutic class and the "fixes" performed to the CMS data to infer values when they are either missing for a quarter or were clearly erroneous. The volume of claims involved in the "fixes" is small (see "Methods" discussion). These "fixes" enabled us to make reasonable predictions of the amount billed for drugs in a therapeutic class over time. These fixes are conservative, but still may result in modest underestimation of rebate amounts for some therapeutic classes.

<sup>16</sup> The Medicaid rebate for brand medications was adjusted for "best price" when a manufacturer contracted with a commercial payer to provide medication at a price lower than AMP minus 15.1%. In this case, the Medicaid rebate became the difference between AMP and BP. This could result in rebates much greater than 15.1%. The CPI adjustment tracked the inflation of the paid amount for a medication from a

base period to the time at which the claim was paid. If the inflation was greater than the consumer price index, the difference was added to the Medicaid rebate owed to the State.



#### Supplemental Rebates

Many Medicaid programs solicited rebates directly from participating manufacturers to supplement the CMS rebates for their preferred drugs. Supplemental rebates enhance the CMS rebates and contribute to additional reductions in the net cost of preferred drugs. These rebates are more stable and could limit the variability associated with the fluctuations of the CMS rebates. However, at this time supplemental rebates are not a factor in the Indiana Medicaid PDL and therefore have no impact on the reported results.

#### Preferred Product Selection

Preferred drug selections are based on initial comparisons of clinical efficacy and safety, followed by a comparison of the relative economic benefits of the medications in each therapeutic class. Due to superior clinical efficacy, there are times when the selected "preferred" drugs were more costly (had higher prices or significantly lower rebates) than the nonpreferred drugs in the class so that switching to preferred drugs actually increased the State's net cost.

As noted in the "Results" section, the preferred drug selection process created 20 PDL classes containing either all preferred drugs, no preferred drugs, or a mix of preferred drugs representing a very high share of the total number of claims in the class. In those situations, there are generally few opportunities to secure positive savings through the shifting of claims volumes to less costly drugs, and in fact only 5 of the 20 classes with limited savings opportunities show positive net savings. Even among classes with all preferred drugs (no nonpreferred drugs) on the PDL, there were market share changes affecting net savings due to various factors that alter prescribing patterns. These factors include new products coming to market, as well as manufacturer efforts promoting the utilization, and prescribing of particular products. The effect of changes among preferred drugs could be significant.

The Indiana Medicaid Therapeutics Committee and DUR Board have a regular schedule for the review of the performance of preferred drug lists and made changes to a number of classes that became effective subsequent to September 2003. It is expected that the impact of these adjustments would be evident in a future study.

#### Price Changes and Other Cost Factors

As indicated above, a Preferred Drug List program is expected to derive savings by shifting prescribing and utilization habits to preferred drugs. Accordingly, the method used to evaluate savings should capture the effects of market changes while controlling for other determinants of cost and cost change. Price and rebate changes affect the ACS savings estimates only when they changed the relative net expense of drugs that were being switched from nonpreferred to preferred in a given month. If there were shifts to or from drugs having a month-to-month change in their net cost relative to other drugs in a class, ACS' method would capture the net cost savings/increases associated with movement to the less expensive or more costly drugs. If the drug mix in a therapeutic



class remained stable, then changes in ingredient prices, unit rebate amounts or copayments would not alter the calculated net savings (see "Methods" section).

Inflation, a cause of price change, is an important determinant of pharmacy expenditure growth. The cost-savings methodology used in this report takes into account inflation by estimating net savings based on the average net cost of drugs in a month of service. This methodology does not estimate savings based on any month-to-month change in average expenditure or average rebate which might be due to price inflation or rebate changes generated by manufacturers.

#### Utilization

Utilization (number of claims) directly affects savings estimates. Savings estimates are proportional to the total number of claims in a PDL class. The savings magnitudes may naturally fluctuate with changes in the number of eligible Medicaid members, seasonal variation in usage, or with any change in the number of claims per user in a given month for each quarter that savings are calculated.

#### Limitations

There is nothing inherent in the design of a preferred drug program that causes overall utilization increases. The program does not promote the new use of particular drugs (i.e., a PDL is not intended to encourage the use of a drug that has not been previously in use) rather an intervention occurs when a prescription for a nonpreferred drug is being processed. At this point in time, the nonpreferred medication may be dispensed, the prescription may be changed to a preferred medication, or the therapy may be terminated. Thus, there is the intrinsic possibility of some utilization decline in association with a PDL intervention. If there is any decrease in utilization, the calculated savings will decline accordingly. If the reduction in utilization is due to reduction of inappropriate utilization by the PDL intervention, then there are real utilization savings for the State in the form of fewer overall claims. This methodology does not adjust the PDL savings estimates to capture such program savings. It is very difficult to discern the extent to which any observed reduction in utilization in a PDL class was due to the intervention or to other factors. Therefore, the estimates presented may underestimate the program savings. Additionally, if prescribing practitioners switch their patients to the preferred drug, or start prescribing the preferred drug before the implementation of each PDL phase, the methodology does not capture the potential savings. There was an overall 4% shift from January 2002 to July 2002 to prescribing preferred agents prior to program implementation.

#### Results

Overall, the PDL program significantly increases the utilization of preferred drugs relative to their nonpreferred alternatives. In January 2002, 7-months prior to PDL implementation and education about the PDL program, 75.2% of the claims were for preferred drugs. By July 2002, the month preceding implementation of the first therapeutic classes on PDL, the preferred claim-share had already increased to 79%. By



September 2003, the preferred claim-share had increased to almost 95.8% (See Table 4.1).

The change in market share shift toward preferred drugs yields financial benefits for the State of Indiana. Based on the analysis of the PDL program for 50 classes between August 2002 and August 2003<sup>17</sup>, ACS estimates the total annualized<sup>18</sup> expenditure savings to be \$12.4 million (see Table 4.2). CMS rebate reductions associated with those classes estimated to be \$3.5 million, resulting in net pharmacy benefit program savings of about \$8.9 million. The net pharmacy benefit savings represented 4.4% of total net expenditures projected had the PDL program not been instituted.

Twenty of these 50 classes provide limited savings potential due to the medications selected as preferred.

- Seven classes have all preferred drugs on the list (i.e., all medications in the class were identified as preferred).
- Two classes have no preferred drugs on the list.

payments plus the estimated payment savings for the period).

• Eleven classes are structured such that the preferred drug market shares exceed 95% in the month prior to PDL implementation.

If these classes with limited potential for savings were excluded, expenditure savings would have risen to 8.4% of expected expenditures (shown in Table 4.2).

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would have been expected had there been no savings/rebate changes over a 1-year period (e.g., observed

<sup>&</sup>lt;sup>17</sup> In addition to the 50 classes considered in this analysis, the Influenza Drugs sub-class of the W5A therapeutic class was implemented on August 8, 2003, but it did not have enough data (2 claims) to analyze. The NSAID/COX II sub-class of the S3B therapeutic class was not implemented until September 17, 2003 and, likewise, did not have sufficient observable experience to be included in this analysis.

<sup>18</sup> Because different classes had been operational for periods ranging from less than 1 month to just over 13 months at the close of the period studied, the observed results were annualized assuming 12 months of operation for all classes. The expected annual payments/rebates/net expenditures were the values that



### TABLE 4.1

	Perce	Indiana Medicaid PDL Program E ent Preferred Before & After PD			tation
	reice	ent Preienred Belore & Alter PB	Jan-02 % Pre-	Sep-03	1 Month Prior to Each Class' Implementation
lmp	Ther			% Pre-	
Date	Class	PREFERRED DRUGS	ferred	ferred	% Preferred
Aug-02		Z2A - Non-Sedating Antihistamines	24.3%	93.7%	27.19
Sep-02		A4D - ACE Inhibitor	33.1%	98.5%	55.19
0.1.00	D4K	D4K - Proton Pump Inhibitors	34.9%	82.4%	36.39
Oct-02	J7ABC	J7A/B/C - ALPHA/BETA Adrenergic Blockers	94.2%	93.5%	93.89
	A9A	A9A - Calcium Channel Blockers	94.0%	97.6%	96.49
	R1M	R1M - Loop Diuretics	93.1%	99.0%	98.99
D 00	M9P	M9P - Platelet Aggregation Inhibitors	90.1%	100.0%	90.99
Dec-02		C4N - Thiazolidenediones	52.5%	90.1%	51.79
	A4D	A4D - ACE Inhibitor W/Diuretics	21.8%	90.0%	76.79
	A4F	A4F - Angiotensin Receptor Blockers w/Diuretics	50.7%	95.0%	46.49
	A4K	A4K - Ace Inhibitor w/CCB	95.2%	99.0%	93.59
	M4E	M4E - Statins	99.0%	99.6%	99.5%
	H3F	H3F - Triptans	56.1%	93.4%	60.09
	Q9B	Q9B - Benign Prostatic Hypertrophy Agents	100.0%	98.9%	100.09
	J5D	J5D - Beta Agonists	85.4%	96.0%	85.79
	P5A	P5A - Inhaled Glucocorticoids	77.5%	97.7%	79.79
	Q7E Z4B	Q7E/P - Nasal Anti-histamine/Anti-inflammatory Steroids Z4B - Leukotriene Receptor Antagonists	100.0% 99.8%	100.0% 99.9%	100.09 99.99
1 00					
Jan-03		A4F - Angiotensin Receptor Blockers	45.7%	88.5%	41.59
		W1W/X/Y - Cephalosporins	71.7%	99.4%	83.49
	W1D W1Q	W1D - Macrolides	99.7%	100.0%	99.79
	W3B	W1Q - Fluoroquinolones W3B - Antifungals	100.0% 87.4%	100.0% 94.7%	100.09 85.89
Feb-03		H6J - Antiemetic/Antivertigo Agents	96.2%	99.0%	92.89
1 60-03	M9K	M9K - Heparin and Related Products	92.3%	89.0%	95.69
	P4L	P4L - SERM's/Bone Resorption Suppression Agents	62.5%	95.6%	73.99
May-03		C4K - Antidiabetic Agents	99.1%	99.9%	99.39
,	D7L	D7L - Bile Acid Sequestrants	50.6%	71.2%	41.29
	НЗА	H3A - Brand Name Narcotics	89.3%	98.1%	96.5%
	H6H	H6H - Skeletal Muscle Relaxants	54.6%	95.6%	65.89
	M4E	M4E - Fibric Acids	90.9%	95.4%	93.09
	R1A	R1A - Urinary Tract Antispasmodic/Anti Incontinence Age	75.7%	98.3%	87.09
Jul-03	J3A	J3A - Smoking Cessation	69.8%	85.1%	78.79
	L1B	L1B - Systemic Vitamin A Derivatives	79.0%	81.8%	100.09
	L5F	LSF - Antipsoriatics	55.1%	62.3%	100.09
	L9B	L9B - topical Vitamin A Derivitives	97.9%	99.3%	100.09
	N1B	N1B - Hematinics	100.0%	93.8%	100.09
	N1C	N1C - Leukocyte Stimulants	80.0%	95.7%	66.29
	Q6G	Q6G - Miotics/Other intraocular Pressure Reducers	64.7%	75.5%	70.19
	Q6I	Q6I - Eye Antibiotic/Corticosteroid Combos	14.4%	70.4%	16.89
	Q6R	Q6R - Eye Antihistamines	99.8%	100.0%	99.89
	Q6U	Q6U - Ophthalmic Mast Cell Stabilizers	20.7%	40.7%	25.69
	Q6W	Q6W - Ophthalmic Antibiotics	94.3%	83.7%	88.69
	Q8VV	Q8FWV - Otic Antibiotics	97.6%	97.9%	97.59
Aug-03	Q4F	Q4F - Vaginal Antimicrobials	8.7%	59.3%	13.89
	Q4K	Q4K - Topical Estrogen Agents	100.0%	100.0%	100.09
	Q5F	Q5F - Topical Antifungal Agents	64.0%	92.6%	67.39
	W5A	W5A - Anti-Herpetic Agents	41.7%	51.6%	41.29
	W5A	W5A-Influenza Agents	0.0%	0.0%	
	S2B	S2B - NSAIDS / Cox II's	0.0%	0.0%	



#### **TABLE 4.2**

			AN	NUALIZED PROGRA			TIC CLASS WITH PRE	FERRED DRUG LIS	T			
					SHOWING PA	YMENT AND REB					<u> </u>	<u>L</u>
				Savings/Changes ( oths of Full Operation			d Have Been Over S		ts, Rebates and Net s If Program Had Not	Savin	mated Anr gs/Change of Expect	es As
Implemen- tation Date	Therapeutic	Class	Payment Savings	Rebate Changes	Net Expense Savings	Expected Annual Claims	Expected Annual Payments	Expected Annual Rebates	Expected Annual Net Expenses	Payment Savings	Rebate Changes	Net Exper
	<del></del>	edating Antihistamines	\$ 796,552	\$ (1,563,391)		228,199	\$ 13,808,062	\$ 4,542,696	\$ 9,265,366	5.8%		_
9/17/2002	A4D - ACE In	hibitor	\$ 239,540	\$ (187,996)	\$ 51,544	276,378		\$ 1,712,045	\$ 6,221,061	3.0%	-11.0%	0.
		Pump Inhibitors	\$ 6,543,025			265,472				18.8%	-3.6%	_
		m Channel Blockers	\$ 2,814 \$ (95,311)			219,408				0.0% -1.7%	-5.9% 3.7%	_
		PHA/BETA Adrenergic Blockers t Aggrtegation Inhibitors	\$ (95,311) \$ (247,175)			267,232 84,572				-2.8%	3.5%	_
	R1M - Loop I		\$ 27,028			268,499				1.0%		_
12/10/2002	A4D - ACE In	hibitor W/Diuretics	\$ (300)	\$ (2,302)	\$ (2,602)	24,536	\$ 786,088	\$ 147,663	\$ 638,425	0.0%	-1.6%	-0
		ensin Receptor Blockers w/Diuretics	\$ 44,731			30,835				2.7%	-1.7%	_
		hibitor w/CCB	\$ (19,337)			20,204				-1.6%	-3.3%	_
	C4N - Thiazo		\$ (1,359,761) \$ 283,488			83,128 20,647				-13.2% 9.1%	71.0%	_
	J5D - Beta A		\$ 283,488 \$ 1,868,973			336,226				14.3%	-18.8%	_
	M4E - Statins	-	\$ (216,561)			263,731				-0.9%	-1.8%	_
		d Glucocorticoids	\$ 238,929			60,964				3.8%	-7.4%	_
		al Anti-histamine/Anti-inflammatory Ster	\$ (31,402)			81,538	\$ 4,796,707			-0.7%	1.2%	_
		Prostatic Hypertrophy Agents	\$ (4,157)			26,713		\$ 541,518		-0.2%	-0.1%	_
		riene Receptor Antagonists	\$ (18,630)			92,629		\$ 1,774,259		-0.3%	-0.1%	_
	W1D - Macro	ensin Receptor Blockers	\$ (170,665) \$ (42,428)			40,028 140,688				-9.9% -0.7%	33.9% -0.2%	_
	W1Q - Fluoro		\$ (42,428) \$ 80,312			87,305				1.3%	-2.1%	_
		Cephalosporins	\$ 901.394			148,068				17.4%		-
	W3B - Antifu	• •	\$ 720,430			34,720				25.5%	-39.4%	_
2/26/2003	H6J - Antiem	etic/Antivertigo Agents	\$ 91,931	\$ (21,608)	\$ 70,323	6,006	\$ 2,461,586	\$ 1,066,644	\$ 1,394,942	3.7%	-2.0%	. 5
***2/26/2003	M9K - Hepar	in and Related Products	\$ (379,076)	\$ 62,130	\$ (316,946)	17,420	\$ 2,868,251	\$ 376,183		-13.2%	16.5%	_
		s/Bone Resorption Suppression Agents				113,018				-0.7%	-6.6%	-
	C4K - Antidia		\$ (16,131)			150,749				-0.3%	-0.2%	_
		id Sequestrants Name Narcotics	\$ 55,319 \$ 665,416			5,458 950,794				14.5%	-38.4% -4.3%	
		name narcollos al Muscle Relaxants	\$ 937,899			171,950				13.6%	-48.9%	-
	M4E - Fibric .		\$ (98,679)			51,744	\$ 2,596,024			-3.8%	0.0%	
5/14/2003	R1A - Urinar	y Tract Antispasmodic/Anti Incontinenc	\$ 681,181	\$ (94,578)	\$ 586,603	99,451	\$ 7,449,965	\$ 1,591,629	\$ 5,858,336	9.1%	-5.9%	10
7/21/2003	J3A - Smokin	ng Cessation	\$ 37,541	\$ (8,664)	\$ 28,877	8,164	\$ 725,455	\$ 71,390	\$ 654,065	5.2%	-12.1%	4
		nic Vitamin A Derivatives	\$ 4,252			92				10.7%	-14.6%	-
	LSF - Antips		\$ 20,751	\$ (10,923)		3,452				5.1%	-7.6%	-
	N1B - Hemat	Vitamin A Derivitives	\$ 17,702 \$ (267,654)			4,348 9,412				6.5% -4.7%	-32.6% 7.8%	_
		cyte Stimulants	\$ 202,904			764				17.5%		_
		ormation Stimulating Agents	\$ -	\$ -	\$ -	364	\$ 184,198			0.0%	0.0%	-
++7/21/2003	Q6G - Miotic	s/Other intraocular Pressure Reducers	\$ (2,057)	\$ (80,391)	\$ (82,448)	51,348	\$ 2,566,857	\$ 610,539	\$ 1,956,318	-0.1%	-13.2%	-4.
		tibiotic/Corticosteroid Combos	\$ 73,469	\$ (84,473)	\$ (11,004)	4,320	\$ 232,597	\$ 166,199	\$ 66,398	31.6%	-50.8%	-16
***7/21/2003	Q6R - Eye A	ntihistamines	\$ 19,948	\$ (2,124)	\$ 17,824	6,808	\$ 441,779	\$ 163,026	\$ 278,753	4.5%	-1.3%	6
		almic Mast Cell Stabilizers	\$ 36,673			2,416				24.6%		
	Q8FAV - Otic	Aptibiotics	\$ 151,168 \$ (10,342)			33,372				17.6% -0.9%		
		er/H.Pylori Agents	\$ 11,621			29,248 882				5.2%		
		al Antimicrobials	\$ 168,470			10,086				41.1%		
		al Estrogen Agents	\$ (347)			6,402				-0.1%		
8/6/2003	Q5F - Topica	l Antifungal Agents	\$ 334,832			77,142				11.2%	-45.9%	2
		Herpetic Agents	\$ 210,266	\$ 37,542	\$ 247,808	19,572	\$ 1,638,384	\$ 598,318	\$ 1,040,067	12.8%	6.3%	23.
	W5A - Influe	-		-	-							
	S3B - NSAID DL PROGRAI		\$ 12,434,379	\$ (3,524,829)	\$ 8,909,550	4,936,501	\$ 270,872,141	\$ 70,104,418	\$ 200,767,723	4.59%	-5.03%	4.4
		Limited Limited Potential For Market	J 12,434,313	\$ (3,324,023)	\$ 0,303,330	4,330,301	\$ 210,012,141	\$ 10,104,410	\$ 200,101,123	4.3370	-3.03 /8	46.
hare Changes			\$ (136,883)			2,360,481	\$ 115,967,894	\$ 29,425,857	\$ 86,542,036	-0.12%	-1.94%	-0.8
		ubstantial Potential For Change	\$ 12,571,262			2,576,019	\$ 154,904,247				-7.26%	
		erse Savings Potential Potential For Substantial Change and	\$ 636,446	\$ (1,980,304)	\$ (1,343,858)	589,193	\$ 37,436,796	\$ 11,017,627	\$ 26,419,169	1.70%	-17.97%	-5.0
	ses vvitn Both al For Positive		\$ 11,934,816	\$ (972,579)	\$ 10,962,237	1,986,827	\$ 117,467,451	\$ 29,660,934	\$ 87,806,517	10.16%	-3.28%	12.4
		Classes With Limited Potential for Char	ge: Classes with no no	n-nreferred drugs								
			Classes with no pr									
		***	Classes with prefe	rred drugs having r								
			Classes with too lo	w volume or too sh	ort of an operatio	nal period to be e	valuated					
		Classes Starting With Negative Saving	s Potential									



#### **Results by Therapeutic Class & Performance**

The ACS Market Share Change Methodology generated data that enabled analysis of the relative performance of individual therapeutic classes within the preferred drug list. Key data elements are organized into the following Appendices:

- A. Tables with quarterly summary statistics for each therapeutic class. Columns include: observed claim count, observed paid per claim, estimated rebate per claim, estimated net cost per claim, observed total payment, estimated total rebate receipts, estimated net cost, payment savings, rebate amount changes and net savings.
- B. Average Rebate Changes, Payment Savings and Net Savings Per Claim Following Implementation of Preferred Drug List by Therapeutic Class and Month of Service.
- C. Preferred Drugs Market Share by Therapeutic Class and Month of Service.
- D. Claims Affected by Preferred Drug List as Share of Total Pharmacy Claims by Therapeutic Class and Month of Service.
- E. Average Allowed Unit Ingredient Amount Price Change Index by Therapeutic Class and Month of Service.
- F. Average Amount Paid and Average Net Expense Per Pharmacy User by Therapeutic Class and Month of Service.

This section individually reviews 50 of the 52 therapeutic classes for which preferred drug lists were implemented through September 2003. The section summarizes the market share changes and annualized financial performance of each therapeutic class, and offers comments to explain some of the dynamics that affected performance.

The summaries are grouped according to six scenarios of observed payment and rebate changes per claim or by three programmatic features that constrained opportunities for change. In the discussion below, the classes are categorized primarily by the circumstances that existed at the time the preferred drug list was implemented. The performance for many classes changed over time. Variations in performance that occurred were primarily due to changes in unit rebate amounts or pricing changes for one or more medications in the class that were also experiencing market share changes. Some performance changes were related to patterns in preferred drug market share or to market share changes among the preferred drugs in a class. The charts in Appendix B, discussed later illustrate the per-claim patterns discussed below. Appendix C charts the preferred drug market share changes by class. In summary, the scenarios used in the analysis with the number of classes covered were:



- 1. Classes with Positive Payment Savings and Positive Rebate Changes (1 class).
- 2. Classes With Positive Payment Savings that Exceeded Negative Rebate Changes (18 classes).
- 3. Classes with Payment Increases that were Exceeded by Positive Rebate Changes (2 classes).
- 4. Classes with Positive Payment Savings that were Exceeded by Negative Rebate Changes (4 classes).
- 5. Classes with Payment Increases that Exceeded Positive Rebates Changes (1 class).
- 6. Classes Where Payment Increases and Rebate Changes were Negative (4 classes).
- 7. Classes Where Preferred Drug Share Exceeded 95% of all Claims in Class at Program Start (11 classes).
- 8. Classes With All Preferred Drugs (7 classes).
- 9. Classes with No Preferred Drugs, Only Nonpreferred (2 classes).

The savings produced by the first two scenarios were the most desirable to a State Medicaid program because the State's savings were up-front in the form of payment reductions. This was more desirable than paying out more for medications and then waiting several months for the benefit in the form of increased rebate payments (Scenario 3). The last three scenarios would appear to offer limited opportunity for savings or losses. As described below, there were changes among individual drugs in those classes that had an impact on net savings.

# 1. <u>Classes with Positive Payment Savings and Positive Rebate Changes. Switches to preferred medications both decreased the average price paid and increased the average rebate amount received.</u>

<u>Class: W5A – Anti-Herpetic Drugs</u> Implementation month: August 2003

Preferred market share change: From less than 41 percent to nearly 50 percent

Annualized pharmacy payments: \$ 1.6 M
Annualized claim count: 20,000
Annualized payment savings: \$ 210,000
Annualized rebate changes: \$ 38,000
Annualized net savings: \$ 248,000

# 2. <u>Classes with Positive Payment Savings that Exceeded Negative Rebate Changes.</u> Switches to preferred products decreased the average amount paid by an amount greater than the loss of associated rebates.

Class: A4D – ACE Inhibitors

Implementation month: September 2002

Preferred market share change: From less than 40 percent to nearly 99 percent

Annualized pharmacy payments: \$ 7.9 M Annualized claim count: 280,000 Annualized payment savings: \$ 240,000



Annualized rebate changes: - (\$ 188,000) Annualized net savings: \$ 52,000

<u>Class: D4K – Proton Pump Inhibitors</u> Implementation month: September 2002

Preferred market share change: From 35 percent to 85 percent

Annualized pharmacy payments: \$ 34.9 M
Annualized claim count: 265,000
Annualized payment savings: \$ 6.5.M
Annualized rebate changes: - (\$ 0.3 M)
Annualized net savings: \$ 6.2 M

<u>Class: J7A/B/C – ALPHA/BETA Adrenergic Blockers</u>

Implementation month: October 2002

Preferred market share change: From 94 to 95 percent

Annualized pharmacy payments: \$ 5.6 M
Annualized claim count: 267,000
Annualized payment savings: - (\$ 0.95 M)
Annualized rebate changes: \$ 0.33 M
Annualized net savings: - (\$ 0.62 M)

Class: A4D – ACE Inhibitor with Diuretics

Implementation month: December 2002

Annualized preferred market share change: From 25 percent to 90 percent.

Annualized pharmacy payments: \$ 0.8 M
Annualized claim count: 25,000
Annualized payment savings: \$ 300.00
Annualized rebate changes" \$ 2,300.00
Annualized net savings: \$ 2,600.00

Class: H3F – Triptans

Implementation month: December 2002

Annualized preferred market share change: From 55 to 95 percent

Annualized pharmacy payments: \$ 3.1 M
Annualized claim count: 21,000
Annualized payment savings: \$ 283,000
Annualized rebate changes: \$ 83,000
Annualized net savings: \$ 200,000

Class: J5D – Beta Agonists

Implementation month: October 2002

Annualized preferred market share change: From 88 to 98 percent

Annualized pharmacy payments: \$13.1 M
Annualized claim count: 336,000
Annualized payment savings: \$ 1.9 M
Annualized rebate changes: \$ 0.7 M



Annualized net savings: \$ 1.2 M

Class: A4F – ARBs with Diuretics

Implementation month: January 2003

Annualized preferred market share change: 48 to 98 percent

Annualized pharmacy payments: \$ 1.7 M
Annualized claim count: 31,000
Annualized payment savings: \$ 45,000
Annualized rebate changes: - (\$ 10,000)
Annualized net savings: \$ 35,000

Class: P5A – Inhaled Glucocorticoids

Implementation month: December 2002

Annualized preferred market share change: From 75 percent to 98 percent

Annualized pharmacy payments: \$ 6.3 M
Annualized claim count: 62,000
Annualized payment savings: \$ 239,000
Annualized rebate changes: - (\$ 138,000)
Annualized net savings: \$ 101,000

Class: W1W/X/Y -- Cephalosporins

Implementation month: January 2003

Annualized preferred market share change: From 93 to 99 percent

Annualized pharmacy payments: \$ 5.2 M
Annualized claim count: 148,000
Annualized payment savings: \$ 901,000
Annualized rebate changes: - (\$ 451,000)
Annualized net savings: \$ 450,000

Class: W3B -- Antifungals

Implementation month: January 2003

Annualized preferred market share change: From 85 to 96 percent

Annualized pharmacy payments: \$ 2.8 M
Annualized claim count: 35,000
Annualized payment savings: \$ 720,000
Annualized rebate changes: - (\$ 312,000)
Annualized net savings: \$ 408,000

Class: H6J -- Antiemetics

Implementation month: February 2003

Annualized preferred market share change: From 96 to 99 percent

Annualized pharmacy payments: \$ 2.5 M
Annualized claim count: 6,000
Annualized payment savings: \$ 92,000
Annualized rebate changes: - (\$ 22,000)
Annualized net savings: \$ 70,000



#### Class: D7L – Bile Acid Sequestrants

Implementation month: May 2003

Annualized preferred market share change: From 40 to 78 percent

Annualized pharmacy payments: \$ 382,000
Annualized claim count: 5,000
Annualized payment savings: \$ 55,000
Annualized rebate changes: - (\$ 30,000)
Annualized net savings: \$ 25,000

#### Class: H6H – Skeletal Muscle Relaxants

Implementation month: May 2003

Annualized preferred market share change: From 66 to 96 percent

Annualized pharmacy payments: \$ 6.9 M
Annualized claim count: 172,000
Annualized payment savings: \$ 938,000
Annualized rebate changes: - (\$ 557,000)
Annualized net savings: \$ 381,000

#### Class: R1A – Urinary Tract Antispasmodics

Implementation month: May 2003

Annualized preferred market share change: From 87 to 98 percent

Annualized pharmacy payments: \$ 7.4 M
Annualized claim count: 99,000
Annualized payment savings: \$681,000
Annualized rebate changes: - (\$ 95,000)
Annualized net savings: \$586,000

#### Class: J3A – Smoking Cessation Drugs

Implementation month: July 2003

Annualized preferred market share change: From 79 to 87 percent

Annualized pharmacy payments: \$725,000
Annualized claim count: 8,000
Annualized payment savings: \$38,000
Annualized rebate changes: - (\$9,000)
Annualized net savings: \$29,000

#### Class: N1C – Leukocyte Stimulants

Implementation month: July 2003

Annualized preferred market share change: From 66 to 98 percent

Annualized pharmacy payments: \$ 1.2 M
Annualized claim count: 1,000
Annualized payment savings: \$ 203,000
Annualized rebate changes: - (\$ 27,000)
Annualized net savings: \$ 176,000



<u>Class: Q4F – Vaginal Antimicrobials</u> Implementation month: August 2003

Annualized preferred market share change: From 14 to 59 percent

Annualized pharmacy payments: \$410,000
Annualized claim count: 10,000
Annualized payment savings: \$168,000
Annualized rebate changes: - (\$92,000)
Annualized net savings: \$76,000

<u>Class: Q5F – Topical Antifungal Drugs</u> Implementation month: August 2003

Annualized preferred market share change: From 67 to 93 percent

Annualized pharmacy payments: \$ 3.0 M
Annualized claim count: 77,000
Annualized payment savings: \$335,000
Annualized rebate changes: - (\$286,000)
Annualized net savings: \$49,000

# 3. <u>Classes With Payment Increases That Were Exceeded by Positive Rebate</u> <u>Changes - Where switches to preferred drugs increased the amount of rebates</u> <u>received more than the increased payments caused by switching to higher priced</u> <u>medications.</u>

<u>Class: C4N – TZDs (Thiazolidinediones):</u> Implementation month: December 2002

Preferred market share change: From 50 to 98 percent

Annualized pharmacy payments: \$10.3 M
Annualized claims count: 83,000
Annualized payment savings: - (\$ 1.4 M)
Annualized rebate changes: \$ 2.1 M
Annualized net savings: \$ 0.7 M

Class: A4F – ARBs (Angiotensin Receptor Blockers)

Implementation month: January 2003

Preferred market share change: From 42 to 96 percent

Annualized pharmacy payments: \$10.3 M
Annualized claims count: 40,000
Annualized payment savings: - (\$171,000)
Annualized rebate changes" \$176,000
Annualized net savings: \$5,000



## 4. <u>Positive Payment Savings that were Exceeded by Negative Rebate Changes –</u> Where the reduction in rebate receipts was greater than the payment reduction.

<u>Class: Z2A – NSAs (Non-Sedating Antihistamines)</u>

Implementation month: August 2002

Preferred market share change: From 25 to 95 percent

Annualized pharmacy payments: \$13.8 M
Annualized claims count: 228,000
Annualized payment savings: \$ 0.8 M
Annualized rebate changes: - (\$ 1.6 M)
Annualized net savings: - (\$ 0.8 M)

#### <u>Class: Q6I – Eye Antibiotic/Corticosteroid Combinations</u>

Implementation month: July 2003

Annualized preferred market share change: From 17 to 72 percent

Annualized pharmacy payments: \$233,000
Annualized claim count: 4,000
Annualized payment savings: \$73,000
Annualized rebate changes: - (\$84,000)
Annualized net savings: - (\$11,000)

#### Class: Q6U – Ophthalmic Mast Cell Stabilizers

Implementation month: July 2003

Annualized preferred market share change: From 26 to 41 percent

Annualized pharmacy payments: \$149,000
Annualized claim count: 2,000
Annualized payment savings: \$37,000
Annualized rebate changes: - (\$43,000)
Annualized net savings: - (\$6,000)

#### <u>Class: Q6W – Ophthalmic Antibiotics</u>

Implementation month: July 2003

Annualized preferred market share change: From 85 to 84 percent

Annualized pharmacy payments: \$900,000
Annualized claim count: 33,000
Annualized payment savings: \$151,000
Annualized rebate changes: - (\$170,000)
Annualized net savings: - (\$ 19,000)



# 5. <u>Classes with Payment Increases That Exceeded Positive Rebate Changes. The increased payment for preferred drugs was only partially offset by increased rebate receipts.</u>

<u>Class: M9P – Platelet Aggregation Inhibitors</u>

Implementation month: October 2002

Preferred market share change: From 91 to 99 percent

Annualized pharmacy payments: \$ 8.7 M
Annualized claims count: 85,000
Annualized payment savings: - (\$ 247,000)
Annualized rebate changes" \$ 87,000
Annualized net savings: - (\$ 160,000)

# 6. <u>Classes with Payment Increases and Negative Rebate Changes -- Where there was an increase in payments as well as a reduction in rebates.</u>

<u>Class: A4K – ACE Inhibitors with CCB</u> Implementation month: December 2002

Preferred market share change: from 95 to 99 percent

Annualized pharmacy payments:\$ 1.2 M
Annualized claims count: 20,000
Annualized payment savings: - (\$ 19,000)
Annualized rebate changes: - (\$ 13,000)
Annualized net savings: - (\$ 32,000)

<u>Class: P4L – Bone Resorption Drugs</u> Implementation month: February 2003

Preferred market share change: From 71 to 96 percent

Annualized pharmacy payments: \$ 7.3 M
Annualized claims count: 113,000
Annualized payment savings: - (\$ 54,000)
Annualized rebate changes: - (\$ 113,000)
Annualized net savings: - (\$ 167,000)

Class: M4E – Fibric Acids

Implementation month: May 2003

Preferred market share change: From 93 to 95 percent

Annualized pharmacy payments: \$ 2.6 M
Annualized claims count: 52,000
Annualized payment savings: - (\$ 99,000)
Annualized rebate changes: - (\$ 100)
Annualized net savings: - (\$ 99,100)



Class: Q6G – Miotics/Other Intraocular Pressure Reducers

Implementation month: July 2003

Preferred market share change: From 70 to 78 percent

Annualized pharmacy payments: \$ 2.6 M
Annualized claims count: 52,000
Annualized payment savings: - (\$ 2,000)
Annualized rebate changes: - (\$ 80,100)
Annualized net savings: - (\$ 82,100)

#### 7. <u>Classes Where Preferred Drugs Had Over 95% of Market Share At Program</u> Start

Class: A9A – CCBs (Calcium Channel Blockers)

Implementation month: October 2002

Preferred market share change: From 95 to 97 percent

Annualized pharmacy payments: \$10. 2 M
Annualized claims count: 219,000
Annualized payment savings: \$3,000
Annualized rebate changes: - (\$89,000)
Annualized net savings: - (\$86,000)

Class: R1M – Loop Diuretics

Implementation month: October 2002

Preferred market share change: From 99 to almost 100 percent.

Annualized pharmacy payments: \$ 2.6 M
Annualized claims count: 268,000
Annualized payment savings: \$ 27,000
Annualized rebate changes: - (\$ 20,000)
Annualized net savings: \$ 7,000

Class: M4E -- Statins

Implementation month: December 2002

Preferred market share change: Preferred drugs had over 99 percent market share at start

Annualized pharmacy payments: \$ 24 M
Annualized claims count: 264,000
Annualized payment savings: - (\$ 217,000)
Annualized rebate changes" - (\$ 124,000)
Annualized net savings: - (\$ 341,000)



#### Class: Z4B – Leukotriene Receptor Antagonists

Implementation month: December 2002

Preferred market share change: Preferred drugs had over 99 percent market share at start

Annualized pharmacy payments: \$ 7.3 M
Annualized claims count: 93,000
Annualized payment savings: - (\$ 19,000)
Annualized rebate changes" - (\$ 2,000)
Annualized net savings: - (\$ 21,000)

#### <u>Class: W1D – Macrolide Antibiotics</u>

Implementation month: January 2003

Preferred market share change: Preferred drugs had over 99 percent market share at start

Annualized pharmacy payments: \$ 5.8 M
Annualized claims count: 141,000
Annualized payment savings: - (\$ 42,000)
Annualized rebate changes" - (\$ 3,000)
Annualized net savings: - (\$ 45,000)

#### Class: M9K – Heparin

Implementation month: February 2003

Preferred market share change: From 95 to maximum of 98 percent

Annualized pharmacy payments: \$ 2.9 M
Annualized claims count: 17,000
Annualized payment savings: - (\$379,000)
Annualized rebate changes: \$ 62,000
Annualized net savings: - (\$317,000)

### Class: C4K – Anti-Diabetic Drugs

Implementation month: May 2003

Preferred market share change: Preferred drugs had over 99 percent market share at start

Annualized pharmacy payments: \$4.7 M
Annualized claims count: 151,000
Annualized payment savings: - (\$16,000)
Annualized rebate changes: - (\$2,000)
Annualized net savings: - (\$18,000)

#### Class: H3A – Brand name Narcotics

Implementation month: May 2003

Annualized preferred market share change: From 97 to 98 percent

Annualized pharmacy payments: \$ 37.3 M
Annualized claim count: 951,000
Annualized payment savings: \$ 665,000
Annualized rebate changes: - (\$ 385,000)
Annualized net savings: \$ 280,000



#### Class: L9B – Topical Vitamin A Derivatives

Implementation month: July 2003

Preferred market share change: Preferred drugs had 100 percent market share at start

despite there being one other drug in class identified as nonpreferred.

Annualized pharmacy payments: \$272,000
Annualized claims count: 4,000
Annualized payment savings: \$18,000
Annualized rebate changes" - (\$ 31,000)
Annualized net savings: - (\$ 13,000)

#### Class: Q6R – Eye Antihistamines

Implementation month: July 2003

Preferred market share change: Preferred drugs 99 percent at implementation.

Annualized pharmacy payments: \$442,000
Annualized claims count: 7,000
Annualized payment savings: \$20,000
Annualized rebate changes" - (\$2,000)
Annualized net savings: \$18,000

## Class: Q6F/W – Otic Antibiotics

Implementation month: July 2003

Preferred market share change: Remained essentially constant at 98 percent

Annualized pharmacy payments: \$ 1.1 M
Annualized claims count: 29,000
Annualized payment savings: - (\$ 10,000)
Annualized rebate changes: - (\$ 33,000)
Annualized net savings: - (\$ 43,000)

#### 8. Classes with No Nonpreferred Drugs

Class: Q7P/P7E – Nasal Anti-Inflammatory Steroids

Implementation month: December 2002

Preferred market share change: None possible. Shifts occurred among preferred drugs

only.

Annualized pharmacy payments: \$ 4.8 M
Annualized claims count: 82,000
Annualized payment savings: - (\$ 31,000)
Annualized rebate changes: \$ 28,000
Annualized net savings: - (\$ 5,000)

#### Class: Q9B – BPH (Benign Prostatic Hypertrophy Drugs)

Implementation month: December 2002

Preferred market share change: None possible. Shifts occurred among preferred drugs

only.

Annualized pharmacy payments: \$ 1.7 M



Annualized claims count: 27,000
Annualized payment savings: - (\$ 4,000)
Annualized rebate changes: - (\$ 400)
Annualized net savings: - (\$ 4,400)

#### Class: W1Q -- Fluoroquinolones

Implementation month: January 2003

Preferred market share change: None possible. Shifts occurred among preferred drugs

only.

Annualized pharmacy payments: \$ 6.0 M
Annualized claims count: 87,000
Annualized payment savings: \$ 80,000
Annualized rebate changes: - (\$ 47,000)
Annualized net savings: \$ 33,000

#### Class: L1B – Systemic Vitamin A Derivatives

Implementation month: July 2003

Preferred market share change: None possible. Shifts occurred among preferred drugs

only.

Annualized pharmacy payments: \$40,000
Annualized claims count: 90
Annualized payment savings: \$4,000
Annualized rebate changes: - (\$6,000)
Annualized net savings: - (\$2,000)

#### Class: L5F – Antipsoriatics

Implementation month: July 2003

Preferred market share change: None possible. Shifts occurred among preferred drugs

only.

Annualized pharmacy payments: \$411,000
Annualized claims count: 3,000
Annualized payment savings: \$21,000
Annualized rebate changes: - \$11,000
Annualized net savings: \$10,000

#### Class: N1B – Hematinics

Implementation month: July 2003

Preferred market share change: None possible. Shifts occurred among preferred drugs

onlv.

Annualized pharmacy payments: \$ 5.7 M
Annualized claims count: 9,000
Annualized payment savings: - (\$268,000)
Annualized rebate changes: \$103,000
Annualized net savings: - (\$165,000)



Class: Q4K – Topical Estrogen Drugs Implementation month: August 2003

Preferred market share change: None possible. Shifts occurred among preferred drugs

only.

Annualized pharmacy payments: \$364,305 Annualized claims count: 6,000 Annualized payment savings: - (\$ 350) Annualized rebate changes: - (\$ 7,000) Annualized net savings: - (\$ 7,350)

#### 9. Classes with No Preferred Drugs

#### Class: P4B – Bone Formation Stimulating Drugs

Implementation month: July 2003

Preferred market share change: None possible. There was only one (nonpreferred) drug

on list.

Annualized pharmacy payments: \$184,000
Annualized claims count: 400
Annualized payment savings: \$ 0
Annualized rebate changes: \$ 0
Annualized net savings: \$ 0

### <u>Class: D4F – Antiulcer/H. Pylori Drugs</u>

Implementation month: August 2003

Preferred market share change: None possible.
Annualized pharmacy payments: \$224,000
Annualized claims count: 900
Annualized payment savings: \$11,500
Annualized rebate changes: - (\$500)
Annualized net savings: \$11,000

### Conclusions on PDL Program Savings

The Indiana Medicaid Preferred Drug List Program as implemented through September 2003 involved 52 therapeutic classes. The PDL savings analysis covered 50 of the 52 classes, because one had very few claims following implementation and one had less than a full month following implementation in which to observe results. The program succeeded in increasing the share of preferred drugs relative to their nonpreferred alternatives from 75.2% in January 2002 to 95.8% by September 2003. This shift was associated with annualized payment savings of \$12.4 M and annualized rebate reductions of \$3.5 M that reduced overall net expenditures by \$8.9 M. This represents about 4.4% of the projected annualized net expenditures had the PDL program not been instituted for the 50 classes.



The program included several therapeutic classes with very limited opportunities for shifting from nonpreferred to preferred medications. Some of these classes experienced cost increases rather than cost savings because of changes among the preferred medications. The trends indicated that prescribers, independent of the initiative, switched users to more costly alternatives. If those classes were excluded, and only classes with opportunities for changing medications from nonpreferred to preferred drugs were evaluated, the annualized net savings would increase to about 8.4% in applicable net expenditures.

The program also included several classes where the net costs per claim for the preferred medications were greater than the net costs of the nonpreferred drugs. In those classes, the preferred drugs were considered clinically superior and safer than the lower cost drugs in the class. Shifting a prescription from nonpreferred to preferred in those classes increased the net cost.

Given the ability of the PDL program to increase preferred drug market share, the choice of therapeutic classes with opportunities for such shifts and the selection of the most cost-effective drugs as preferred were crucial to fully realizing the potential financial benefits of the preferred drug list. The selected drugs must be clinically appropriate to the needs of the target population and the expected net cost (expected payment amount per claim less expected rebate amount per claim) of preferred drugs must be lower than that of the nonpreferred drugs that they are likely to be replacing. It is necessary to consider both the price paid to pharmacies and the federal rebates received from manufacturers in assessing relative net costs. If the average net cost for preferred drugs in a class is more costly than the nonpreferred drugs, then shifting to preferred drugs increases rather than decreases costs.

To produce substantial savings with a preferred drug list, it is also important to limit the number of drugs deemed as "preferred." Overly inclusive lists limit savings since they reduce the number of nonpreferred drug prescriptions eligible for change.

The T Committee and DUR Board review bi-annually each of the therapeutic classes and have already made many modifications to enhance the effectiveness of the PDL. Implementation of these enhancement changes began in September 2003 and was too late to be observable in this PDL savings analysis.

With respect to the future, predictive modeling tools are now available to explore the financial implications of alternative formulations of preferred drugs in a therapeutic class. Such tools can be used to help determine the most cost-effective combination of preferred drugs, given the clinical requirements of the class. Changes over time in federal rebates, manufacturer prices, and preferred drug market shares, all of which could jeopardize future savings, need to be monitored on a regular basis to watch for changes that may point to a need for program modifications. Those findings will be considered by the T Committee and DUR Board in their biannual reviews.